Exhibit E

Appendix of Exhibits to Amended Complaint

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EXHIBIT 46

Letter from SFP to Stephen Ostroff (Feb 4, 2016)

CONFIDENTIAL

February 4, 2016

Stephen Ostroff, M.D., Acting Commissioner of Food and Drugs
Robert M. Califf, M.D., Deputy Commissioner for Medical Products and Tobacco
Janet Woodcock, M.D., Director of the Center for Drug Evaluation and Research
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Drs. Ostroff, Califf, and Woodcock,

The following 30 organizations write to ask the U.S. Food and Drug Administration (FDA) to lift the Risk Evaluation and Mitigation Strategy (REMS) imposed in 2000 when it approved the use of Mifeprex© (mifepristone) for pregnancy termination, and to extend the indicated use through a gestational age of 70 days. In the 15 years since mifepristone's approval, multiple clinical trials, dozens of studies, and extensive experience across the globe have confirmed the FDA's finding that mifepristone is a safe and reliable method of abortion. Studies have shown that mifepristone in combination with misoprostol is up to 99% effective for first trimester abortion[1,2] and that serious complications are rare.[3] The steady increase in use of medication abortion – now 23% of U.S. abortions – shows that many women prefer this option, and that it has the ability to improve access to abortion, even in states with restrictive laws. Provider interest in offering mifepristone has also increased substantially: in 2011, 59% of abortion providers offered early medication abortions, up from 33% in 2008.[4] This growing use of medication abortion has made a major difference in people's lives. We thank the FDA for ensuring mifepristone is available on the market for patients' reproductive health care needs.

However, many who could benefit from mifepristone still do not have access to it due to multiple types of restrictions, including those required by the FDA. In November 2015, a group of organizational and individual researchers submitted a letter to the FDA (hereinafter "Technical Letter") asking the agency to lift the REMS on mifepristone and extend the indicated use to 70 days gestational age, presenting data showing that the current restrictions and limited gestational age indication are unnecessary for the safe and effective use of the drug for pregnancy termination.

As policy, advocacy, social science, research, and academic organizations, we ask the FDA to consider the substantial evidence presented in the Technical Letter, alongside the burdens that the REMS and the label's 49-day gestational age indication place on patient access, which we describe here. The FDA held a public meeting in October 2015 to discuss improving patient access to drugs under REMS,[5] evidencing the agency's own awareness of patient burden caused specifically by restrictions imposed under REMS. We applaud these efforts and urge the FDA to use its regulatory authority to remove the medically unnecessary barriers to mifepristone.

Mifepristone underwent a lengthy approval process in the late 1990s, during which it became subject to a rarely-used approval mechanism: Subpart H of the FDA's Title 21, Chapter 314 regulations. Subpart H is used primarily for drugs with very serious and well-documented safety concerns.[6] In 2007, Subpart H restrictions on all drugs were converted automatically into a Risk Evaluation and Management Strategy (REMS),[7] a mechanism created by Congress whereby FDA can impose Elements to Assure Safe Use (ETASU). Under this law, as the Agency stated in preparation for its October 2015 meeting on REMS,[8] Congress mandated that the FDA engage in a balancing analysis to ensure that the risks mitigated by a REMS program do not unduly burden patients' access to health care:

> [E]lements to assure safe use [ETASU] ... shall–
>
> (A) be commensurate with the specific serious risk listed in the labeling of the drug;
>
> ...
>
> (C) considering such risk, not be unduly burdensome on patient access to the drug, considering in particular–
>
> (i) patients with serious or life-threatening diseases or conditions; and
>
> (ii) patients who have difficulty accessing health care (such as patients in rural or medically underserved areas)….[9]

Although the FDA may have decided 15 years ago that the balance of risk and burden came out in favor of restricting mifepristone's indicated use and distribution, today both science and the current conditions surrounding patient access to abortion care call strongly for a reevaluation of the mifepristone label and REMS restrictions, especially its Elements to Assure Safe Use (ETASU).

We support the following changes to the mifepristone label:

- The drug should be indicated for use in medication abortions beyond 49 days gestation.
- The recommended dose regimen should be mifepristone 200 mg followed 24-48 hours later by misoprostol 800 mcg.
- The location where the patient should take these drugs should not be restricted.
- An in-person visit should be indicated as not always necessary for follow-up assessment.
- Any licensed health care provider should be able to prescribe the drug.

We expand below upon further specific changes that should be made based on scientific evidence of mifepristone's safety and efficacy, as well as the numerous burdens on patients' access to abortion care that would be greatly alleviated if the REMS were eliminated and the gestational age indication in the label were increased to 70 days.

1. **Eliminate the REMS and ETASU for mifepristone.**
   a. **Expand dispensing venues.** The ETASU state that mifepristone may only be dispensed to patients in a clinic, medical office, or hospital, and not through pharmacies.[10] The Technical Letter discusses why this requirement is not medically warranted. The requirement should be removed entirely, so that mifepristone can also be distributed via retail pharmacies like other prescription medications, in addition to being directly distributed to providers.

      This requirement significantly curtails mifepristone's potential to expand patient access to abortion care. The up-front costs (including substantial costs for pre-ordering the drug) and logistical requirements (e.g., increased staffing at provider offices) are a burden to providers and, therefore, deter some health care providers from offering medication abortion. When fewer providers are willing to stock mifepristone in their offices because of the REMS and ETASU, fewer patients can access medication abortion. In some cases this requirement may also force the patient to make an unnecessary visit to a clinic, medical office, or hospital to pick up the medication, rather than being able to pick up an order called into a pharmacy. This requirement is especially significant in underserved and rural areas where access to a health care provider is already difficult, and for those with low incomes for whom taking off work or getting to a provider multiple times in short order is impossible due to cost or family needs.[11] The Turnaway Study, a prospective longitudinal study conducted by Advancing New Standards in Reproductive Health (ANSIRH) at the University of California-San Francisco examining the effects of unintended pregnancy on individuals' lives, demonstrates that the majority of people who seek abortion care are already in difficult financial situations, and are

disproportionately people of color.[12] Costly and unnecessary visits to the doctor significantly increase financial and logistical burdens for these individuals and communities.

Any venue expansion, however, should not preclude the direct distribution of mifepristone to providers who want to dispense from their clinical settings. In many places, pharmacy refusal laws allow pharmacists to decline to fill prescriptions for reproductive health drugs such as emergency contraception and birth control, and federal policy allows providers to refuse to provide abortions.[13] So, although pharmacists' ability to dispense mifepristone would expand patient access to medication abortion in places where providers cannot easily store mifepristone in their offices, providers should retain the option to have mifepristone directly distributed to their offices to ensure continued access to medication abortion for those living in places where pharmacists can refuse to fill mifepristone prescriptions.

b. **Eliminate the Prescriber Agreement certification requirement.** Under the REMS and ETASU, providers must have a physician supervisor submit a Prescriber Agreement form to the drug's distributor attesting: 1) that mifepristone will only be provided by or under the supervision of a physician; and 2) that the physician can assess pregnancy duration, 3) diagnose ectopic pregnancies, and 4) make a plan for a patient to have surgical intervention if necessary.[10] This requirement should be eliminated for several reasons:

i. *The Prescriber's Agreement is unnecessary for the safe dispensation of mifepristone.* As the Technical Letter explains, health care professionals are already subject to many laws, policies, and ordinary standards of practice that ensure they can accurately and safely understand and prescribe medications. Provider certification is not required for health care professionals to dispense other drugs, including drugs that carry black box, or boxed, warnings about their medical risks. Accutane, for example, has a boxed warning that describes the potential risks of the drug,[14] but Accutane prescribers are not required to submit a certification form in order to prescribe it. Mifeprex also has a boxed warning[15] and there is no medical reason for a Prescriber's Agreement to be required in addition.

ii. *The Prescriber's Agreement forces providers to identify themselves as abortion providers to a centralized entity (Danco Laboratories) inspected and regulated by the FDA, which could discourage some from offering medication abortion care to their patients*. In 2014, more than half of U.S. health care facilities that provide abortions (52%) experienced threats and other types of targeted intimidation, and one in five experienced severe violence, such as blockades, invasions, bombings, arsons, chemical attacks, physical violence, stalking, gunfire, bomb threats, arson threats, or death threats.[16] Robert Dear's November 27, 2015, standoff at a Planned Parenthood health center in Colorado, which resulted in three deaths, provides one recent and chilling example of anti-abortion violence.[17] Given such escalating harassment and violence against known abortion providers,[18] clinicians may be understandably reluctant to add their names to a centralized database of mifepristone providers.

iii. *The Prescriber's Agreement would be incompatible and unnecessary if there were an expanded distribution system*. If dispensing venues are expanded as proposed in section 1a, ordinary standards of practice and state regulations would govern pharmacists' and providers' distribution of mifepristone, and a specific certification process would be unnecessary. Furthermore, a distribution system that incorporates the Prescriber's Agreement would be extremely difficult to maintain as a practical matter. Pharmacists would need to check the certification status of each prescriber before filling a prescription, which they do not normally have to do when filling other prescriptions.

Alternatively, pharmacists would need to become certified providers themselves, thus facing the deterrence problem of adding their names to a centralized database of mifepristone providers.

iv. *The Prescriber's Agreement as currently written prevents independent non-physician prescribers from being able to prescribe mifepristone without supervision by a physician*. The Prescriber's Agreement currently states that mifepristone "must be provided by or under the supervision of a physician."[19] However, nowhere in the outline piece of the REMS document written by the FDA is the word "physician" used. The REMS references only "providers" and "prescribers." [10] The Prescriber's Agreement's narrow interpretation of the REMS is medically unnecessary and severely limits patients' access to medication abortion care, because non-physician providers must work under physician supervision to prescribe mifepristone. All states give certain advanced practice clinicians prescribing authority, including for controlled substances, and 27 states allow them to dispense medications directly.[20] Advanced practice clinicians provide an increasing proportion of basic health care in the U.S., and several states authorize these clinicians to provide abortion care. If the Agreement is not eliminated, then at least enlarging the pool of health care providers that can submit the Prescriber's Agreement would help improve access and be consistent with individual state law regarding scope of practice. If the FDA does not eliminate the Agreement altogether, it should make clear that any licensed health care provider with prescribing authority is also eligible for certification to prescribe mifepristone.

c. **Remove the confusing and unnecessary Patient Agreement.** The REMS requires that each patient sign a Patient Agreement form before receiving mifepristone. This requirement is medically unnecessary and interferes with the clinician-patient relationship. It should be eliminated entirely.

In addition to being outdated and inconsistent with requirements for drugs with similar safety profiles, the Patient Agreement creates confusion for patients. Except in the few states that require that patients follow the regimen that appears on the mifepristone label, the majority of clinicians use an evidence-based regimen that is different from the regimen described in the label. Requiring a patient to sign an agreement to a treatment plan that differs from the one prescribed by her provider is confusing and could undermine trust in the clinician.

Patients have been using mifepristone safely and effectively according to evidence-based regimens recommended by their clinicians for many years, diverging from the regimen described in the Patient Agreement.[3] A wealth of data and experience since mifepristone's approval have demonstrated that this drug is extremely safe, that clinicians with routine professional training can provide it appropriately, and that patients are able to use it as directed by their health care provider.[21,22] Requiring a patient to sign an agreement to a treatment plan that differs from the one prescribed by her provider may create unnecessary confusion.

d. **Allow evidence-based follow-up assessment.** Under the Federal Food, Drug, and Cosmetic Act, the FDA should ensure that a REMS does not unduly burden patients, especially those in rural or medically underserved areas.[9] However, the documents appended to the REMS (the Medication Guide, Prescriber's Agreement, and Patient Agreement) all indicate the patient should to return to the clinic for follow-up 14 days after the patient takes mifepristone.[10] Such an in-person appointment is not always medically necessary and, when required, creates significant additional costs for patients, who must find time for another appointment at the provider's office and potentially incur substantial costs for travel, childcare, and/or lost wages.

These burdens are often increased for patients living in rural and other medically underserved areas. In 2008, 33% of all abortion patients traveled more than 25 miles to obtain care, and 74% of all patients living in rural areas traveled at least 50 miles to obtain the procedure.[23] Medical technology and telemedicine have advanced considerably since 2000,[24] and a growing body of evidence shows that alternatives to in-person follow-up, such as serum chorionic gonadotropin (hCG), multi-level pregnancy tests, and telephone counseling are safe, effective, and improve access and satisfaction for patients.[25,26,27]

2. **Increase the gestational age for indicated use on the label.**
The current label indicates use of mifepristone through 49 days after the start of the patient's last menstrual period (LMP). The Technical Letter discusses the substantial evidence demonstrating that the evidence-based medication abortion regimen is highly effective later than 49 days LMP, through at least the 10th week (64-70 days) of gestation.[28,29,30] The National Abortion Federation's (NAF) annual *Clinical Policy Guidelines*, which NAF develops by consensus based on a rigorous review of current medical literature and known patient outcomes, recommend that an evidence-based medication abortion regimen be used through 70 days LMP.[31] The time between 49 and 70 days LMP is critical for patient access, as approximately 30% of women who seek an abortion present for care during this time, according to the Centers for Disease Control.[32]

Consider the current legal and social climate

The overall legal and social climate around abortion care intensifies all of the burdens that the mifepristone REMS places on patients and makes it even more critical that the FDA lift medically unnecessary restrictions on the drug. Since mifepristone's approval, a multitude of laws and regulations at the federal and state level have dramatically restricted access to abortion care. In the first five years of this decade alone, states enacted 288 abortion restrictions – more than the entire previous decade.[33] These restrictions are typically unsupported by medical evidence and serve only to reduce access to abortion care.[34] In 2000, the Guttmacher Institute, a nonpartisan research and policy organization that seeks to advance sexual and reproductive health and rights and ensure the highest standard of sexual and reproductive health care, considered 13 states to be hostile to abortion, meaning that those states had 4-5 types of restrictions on abortion. In 2014, the number of states considered hostile had more than doubled, now including more than half of all states. [34]

Providers have increasingly been forced to close their doors as a result of mounting restrictions. There were about 1,800 abortion providers in the U.S. in 2000. Stand-alone abortion clinics constituted 447 (25%) of all providers in 2000, and those clinics provided 71% of all abortions.[35] By 2008, only 378 abortion clinics were still providing 70% of abortions.[36] Abortion clinic closures have accelerated since 2008, as lawmakers began passing restrictions at an unprecedented rate.[37] The Associated Press estimated in June 2015 that 70 abortion clinics had closed in a dozen states since 2010.[38] This wave of state restrictions and clinic closures has continued unabated in the last five years.

Some of these measures specifically block access to medication abortion by invoking the FDA-approved label. North Dakota, Ohio, and Texas currently require mifepristone to be administered solely according to the regimen that appears on the FDA label.[39] The Arkansas legislature just passed a similar law in 2015, though a federal judge issued a temporary restraining order blocking enforcement of the law until a hearing on March 14, 2016.[40] In these states, mifepristone cannot be prescribed in accordance with evidence-based practices developed in the last 15 years,[*] which improve patient access in multiple ways:

- enabling patients to take a lower dose of mifepristone, resulting in fewer side effects and lower cost;

[*]The one deviation that Texas allows from the label is one other dosage amount of Mifeprex and misoprostol.[39]

- allowing patients to take mifepristone, misoprostol, or both at home, and/or confirm termination of pregnancy at home, resulting in fewer visits to the provider;
- and offering medication abortion to patients later than 49 days LMP. [3]

Studies have also shown that these "label laws" have had a negative impact on patient access to abortion. For example, a recent study showed that after passage of laws that restricted use of mifepristone to the FDA label in Texas and Ohio, medication abortion declined dramatically while it rose in New York and California, states without restrictive laws.[41] Furthermore, these laws run counter to the FDA's own guidance, which states that a "package insert is informational only."[42,43,44] As long as the FDA-approved label diverges from evidence-based regimens, states can hide behind it as they restrict access to abortion. If the FDA does not update mifepristone's label to reflect the most current, evidence-based practice, the number of women adversely affected will only increase as additional states pass laws to exploit this discrepancy.

Other state restrictions are not specific to medication abortion, but affect all kinds of abortion care, including access to mifepristone. These medically unnecessary restrictions include the following: requirements that facilities where abortion is provided meet standards for ambulatory surgical centers; physician admitting privileges at local hospitals; and requirements that the patient and prescribing clinician must be in the same physical location, prohibiting the use of telemedicine technology. On top of these legal restrictions, anti-abortion stigma, harassment, and violence deter many health care professionals from providing abortion care. Authorizing distribution of mifepristone in pharmacies could diminish the impact of these barriers and allow providers to offer abortion care without fear of retaliation.

These restrictions, and the concomitant politicization and stigmatization of abortion care, have also seeped into other aspects of health care and prevented progress on the use of mifepristone for other indications. Removing the REMS program would make mifepristone more readily available for non-abortion therapies as well.[45,46]

In summary, the burdens on patient access to medication abortion, exacerbated by the REMS requirements placed on mifepristone, strongly outweigh any medical risk to the patient associated with the drug. In this climate of legal restrictions, clinic closures, and mounting stigma, it is increasingly important that any regulation of mifepristone be based solely on medical evidence, rather than the discretion of politicians who are determined to restrict access to abortion at any price. We recognize that the FDA is not responsible for most restrictions on abortion access. However, whenever the FDA evaluates indications and restrictions on an approved product, it does so in the context of the real-world circumstances in which the product is sold and the condition is treated. We believe this is vital in the case of mifepristone in particular, where the broad landscape of laws regulating abortion has measurable negative impact on the clinical provision of abortion care.

Mifepristone continues to hold immense promise for patient access to a safe and effective early abortion option, but medically unnecessary regulations are impeding its full potential. Extensive scientific and clinical evidence of mifepristone's safety and efficacy, and the ever-increasing burden on patient access to abortion care, clearly demonstrate that mifepristone's REMS program is not needed to protect patients. In light of the FDA's statutory mandate from Congress to consider the burden caused to patients by REMS, and the agency's own stated commitment to ensuring that drug restrictions do not unduly burden patient access, we ask that the FDA lift mifepristone's REMS and amend the label to extend the indicated use to 70 days.

Sincerely,

Advancing New Standards in Reproductive Health (ANSIRH), Department of Obstetrics, Gynecology & Reproductive Sciences, University of California, San Francisco
American Civil Liberties Union
Association of Reproductive Health Professionals
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Carafem
Center for Reproductive Rights
Center on Reproductive Rights and Justice at the University of California, Berkeley, School of Law
Feminist Majority Foundation
Guttmacher Institute
Gynuity Health Projects
Ibis Reproductive Health
Jacobs Institute of Women's Health
Legal Voice
Medical Students for Choice
NARAL Pro-Choice America
National Abortion Federation
National Advocates for Pregnant Women
National Institute for Reproductive Health
National Latina Institute for Reproductive Health
National Network of Abortion Funds
National Partnership for Women and Families
National Women's Health Network
National Women's Law Center
Planned Parenthood Federation of America
Physicians for Reproductive Health
Provide
Reproaction
Reproductive Health Technologies Project
Society of Family Planning

cc:
Valerie Jarrett, Chair, White House Council on Women and Girls
Tina Tchen, Executive Director, White House Council on Women and Girls
Jordan Brooks, Deputy Executive Director, White House Council on Women and Girls
Nancy C. Lee, M.D., Deputy Assistant Secretary of Health, Women's Health, Director of the Office on Women's Health, Department of Health and Human Services
Bobby Clark, Counselor for Public Health and Science, U.S. Department of Health and Human Services, Office of the Secretary

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[41] Sheldon WR, Winikoff B. Mifepristone label laws and trends in use: recent experiences in four US states. *Contraception*, 2015;92:182-85. doi: 10.1016/j.contraception.2015.06.017.
[42] U.S. Food and Drug Administration, Drug Bulletin 12:1, 4-5 (1982) ("The FD&C Act does not… limit the manner in which a physician may use an approved drug …. With respect to its role in medical practice, the package insert is informational only").
[43] Agency Request for Comments: Citizen Petition Regarding the Food and Drug Administration's Policy on Promotion of Unapproved Uses of Approved Drugs and Devices, 59 Fed. Reg. 59820-01 (Nov. 18, 1994) ("FDA has long recognized that physicians and other health care professionals may prescribe approved therapies for unapproved uses").
[44] Agency Comments on Proposed Rule: Applicability of IND Requirements, 52 Fed. Reg. 8798, 8803 (final rule Mar. 19, 1987) (codified at 21 CFR § 312.2) ("As noted in the preamble to the proposed rule, it was clearly the intent of Congress in passing the Federal Food, Drug, and Cosmetic Act that FDA not regulate the practice of medicine, which the agency has consistently viewed as including the use by physicians of marketed drugs for unlabeled indications in the 'day-to-day' treatment of patients. Once a drug product has been approved for marketing, a physician may, in treating patients, prescribe the drug for uses not included in the drug's approved labeling. Control of the practice of medicine in these cases is primarily exercised through State laws affecting medical licensing and practice and through products liability law").
[45] Dzuba IG, Grossman D, Schreiber CA. Off-label indications for mifepristone in gynecology and obstetrics. *Contraception*, 2015;92:203-05, doi: 10.1016/j.contraception.2015.06.021 (showing that data from around the world suggests mifepristone could be used to treat patients with a wide variety of cancers, tumors, and other hormone-sensitive conditions who have exhausted other standard treatments).
[46] Mifepristone Compassionate Use Program. Feminist Majority Foundation website (discussing a program that has been able to help treat a small cadre of eligible patients, but must contend with FDA-mandated paperwork that is onerous to most physicians and creates needless delays in quickly and effectively accessing a potentially life-saving treatment option). http://www.feminist.org/rrights/compassionateuse.asp. Accessed December 21, 2015.

EXHIBIT 47

Whole Women's Health Complaint

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, on behalf of itself, its staff, and its patients; WHOLE WOMAN'S HEALTH, on behalf of itself, its staff, and its patients; WHOLE WOMAN'S HEALTH OF THE TWIN CITIES, LLC, on behalf of itself, its staff, and its patients; BLUE MOUNTAIN CLINIC, on behalf of itself, its staff, and its patients; HELEN WEEMS, APRN-FNP on behalf of herself and her patients; ALL FAMILIES HEALTHCARE, on behalf of itself, its staff, and its patients; and TRUST WOMEN FOUNDATION, on behalf of itself, its staff, and its patients, Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; ROBERT M. CALIFF, M.D., in his official capacity as Commissioner of Food and Drugs; UNITED STATES DEPARTMENT OF HEALTH AND HUMAN SERVICES; and XAVIER BECERRA, in his official capacity as Secretary of the Department of Health and Human Services, Defendants.	Case No. 3:23-cv-00019

COMPLAINT FOR DECLARATORY AND INJUNCTIVE RELIEF

1. In the wake of the overruling of *Roe v. Wade*, Plaintiffs, who are independent abortion providers in Virginia, Montana, and Kansas, have made herculean efforts to provide high-quality, compassionate, patient-centered abortion care. They have done so not only for residents of their states, but also for the thousands of patients forced to travel hundreds of miles for basic healthcare from the 13 states and counting where abortion is now banned, and the many others where it remains severely restricted. Pregnant people who struggle to make ends meet, live in rural areas, and have limited access to healthcare face more barriers than ever to accessing abortion.

These barriers are also particularly severe for people of color and people with disabilities who experience significant disparities in healthcare access and maternal health outcomes.

2. In order to meet the needs of their patients, Plaintiffs rely on the ability to prescribe medication abortion, which is safe and effective, less expensive and less resource-intensive than procedural abortion, and preferred by many patients. Plaintiffs all use a two-drug regimen for medication abortion, where patients take the first drug, mifepristone, followed by a second drug, misoprostol, around 24-72 hours later. Medication abortion, and specifically, provision of mifepristone by advanced practice clinicians (including nurse practitioners and physician assistants) and the availability of medication abortion by mail ("direct to patient telehealth") has been critical to their efforts to meet people's need for abortion care.

3. Not content with—as they claimed—"return[ing] the issue of abortion to the people's elected representatives," *Dobbs v. Jackson Women's Health Org.*, 142 S. Ct. 2228, 2243 (2022), anti-abortion activists have turned their attention to restricting abortion nationwide. Their latest attack is on medication abortion, seeking to curtail its availability anywhere and by any means necessary, including in states where abortion remains legal and even protected.

4. The two-drug medication abortion regimen has been used safely and effectively for the past 23 years by over five million Americans. Despite this strong track record of safety and the well-documented benefits of medication abortion for many patients—including survivors of sexual assault, pregnant people with certain common chronic conditions, and those who prefer to manage their abortion care in a private location—mifepristone has faced unique and discriminatory scrutiny, which has generated significant stigma. From the very beginning, mifepristone has been treated differently from comparable drugs.

5. It is time that defendants the United States Food and Drug Administration ("FDA") and the Department of Health and Human Services ("HHS") follow the science, respect pregnant people's autonomy, and discard the unique set of restrictions known as a Risk Evaluation and Mitigation Strategy ("REMS") it has applied to mifepristone in various guises since its approval. FDA's decision to continue these burdensome restrictions in January 2023 on a drug that has been on the market for more than two decades with only "exceedingly rare" adverse events has no basis in science. It only makes mifepristone harder for clinicians to prescribe, harder for pharmacies to dispense, and harder for patients to access. And, by making mifepristone *seem* uniquely dangerous, FDA's continuing restriction of mifepristone stigmatizes medication abortion and contributes to the chaos anti-abortion activists now sow. Plaintiffs are continuously facing the weaponization of the REMS by anti-abortion activists around the country.

6. Ensuring that access to mifepristone is based on science and the needs of patients has only increased in urgency over the last few weeks. Federal district courts in Texas and Washington have issued competing orders regarding mifepristone's continued accessibility. The Texas order purports to "stay" the effective date of FDA's 2000 approval of mifepristone, which could render it unavailable anywhere. *All. for Hippocratic Med. v. FDA*, No. 2:22-CV-223-Z, 2023 WL 2825871, at *32 (N.D. Tex. Apr. 7, 2023) (the "*Alliance* Case"). A subsequent order from the Fifth Circuit modified the Texas order, purporting to turn back time and reinstate one version of the REMS that was in place prior to 2016—including restricting certified prescribers of mifepristone to physicians only (not advanced practice clinicians) and banning direct to patient telehealth. *All. for Hippocratic Med. v. FDA*, No. 23-10362, 2023 WL 2913725, at *1, *17, *21 (5th Cir. Apr. 12, 2023) (per curiam). Meanwhile, the Washington order enjoins FDA from "altering the status quo and rights" as to the availability of mifepristone under the REMS in place

as of January 2023 in 17 states and the District of Columbia, *Washington v. FDA*, No. 1:23-CV-3026-TOR, 2023 WL 2825861, at *11 (E.D. Wash. Apr. 7, 2023), "irrespective of" the Texas and Fifth Circuit decisions, *Washington v. FDA*, No. 1:23-CV-3026-TOR, 2023 WL 2941567, at *2 (E.D. Wash. Apr. 13, 2023). Anti-abortion activists are continuing with other efforts to threaten mifepristone, including a citizen petition to FDA by Students for Life seeking to have mifepristone's approval revoked because it somehow endangers the environment.[1]

7. Although the Supreme Court has entered a preliminary stay that averts some of the devastating harms that were about to occur due to the trial court decision in the *Alliance* Case, *see Danco Lab'ys, LLC v. All. for Hippocratic Med.*, No. 22A901, 2023 WL 3033177 (U.S. Apr. 21, 2023), threats to the availability of mifepristone continue to loom large—prompting a growing number of states to stockpile large amounts of mifepristone even after the Supreme Court's stay. As Monica Simpson, Executive Director of SisterSong Women of Color Reproductive Justice Collective and an abortion access advocate in Georgia, attested, although access remains for now: "the week-by-week uncertainty of not knowing the fate of this access" remains.[2]

8. Plaintiffs—independent abortion providers with limited resources in hostile states—are caught in the middle of this maelstrom. They provide care in states that are party to neither case and are thus in a particularly precarious and uncertain position. Plaintiffs cannot retool their practices overnight with no notice—healthcare has no on/off switch. They and their patients require clarity around their continued provision of mifepristone.

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[1] Alice Miranda Ollstein, *Anti-Abortion Group Launches New Pill Challenge as SCOTUS Mulls Sweeping Restrictions*, Politico (Apr. 20, 2023, 9:48 A.M.), https://www.politico.com/news/2023/04/19/students-for-life-abortion-scotus-00092771.

[2] Ava Sasani, *The Decision Brought Vows to Keep Fighting from Both Sides of the Abortion Debate*, N.Y. Times (Apr. 21, 2023), https://www.nytimes.com/2023/04/21/us/abortion-pill-supreme-court-reactions.html.

9. No other facet of healthcare is treated in this way, much less any other essential medication with such an established record of safety and efficacy. It is neither rational nor sustainable, especially in light of the unique challenges Plaintiffs now face in the post-*Roe* world.

10. Throughout this chaos, there is one constant: mifepristone remains a highly safe and effective medication and it remains essential for patients. FDA has recognized these basic facts time and again, and yet continues to subject the drug to medically baseless restrictions, prompting repeated attempts to target mifepristone for further restriction or outright removal from the market. Without relief, Plaintiffs remain vulnerable to the continued attacks on medication abortion from anti-abortion activists and state and federal regulators across the country who will continue to weaponize FDA's REMS while they stand.

11. Plaintiffs request that the Court order FDA to remove the REMS restrictions that have, for too long, impeded access to medication abortion, and are the source of the current chaos for people seeking essential abortion care nationwide. In the alternative, Plaintiffs seek an order enjoining Defendants from altering the availability of mifepristone under the January 2023 REMS, to ensure some modicum of certainty and continued patient access to a safe, effective medication that has been repeatedly targeted simply because of its association with abortion.

JURISDICTION AND VENUE

12. The Court has subject matter jurisdiction under 28 U.S.C. § 1331, as this is a civil action arising under federal law, and under 5 U.S.C. § 702, as this is a civil action seeking judicial review of a final agency action.

13. This action for declaratory and injunctive relief is authorized by 28 U.S.C. §§ 2201 and 2202, by Federal Rules of Civil Procedure 57 and 65, and by the inherent equitable powers of this Court.

14. The Court has personal jurisdiction over Defendants pursuant to 28 U.S.C. § 1391(e) because Defendants are agencies and officers of the United States.

15. Venue is proper in this district pursuant to 28 U.S.C. § 1391(e) because this is a judicial district in which Plaintiff Whole Woman's Health Alliance resides and Defendants' policies adversely affect the health and wellbeing of residents in this district.

PARTIES

I. Plaintiffs

Whole Woman's Health Alliance

16. Plaintiff Whole Woman's Health Alliance ("WWHA") is a nonprofit organization committed to providing holistic reproductive care for its patients. It operates Whole Woman's Health of Charlottesville ("WWH of Charlottesville"), a healthcare facility located in Charlottesville, Virginia that provides abortion services up to 16 weeks as dated from the patient's last menstrual period ("LMP"),[3] including medication abortion up to 11 weeks LMP, and miscarriage management. WWH of Charlottesville started providing medication abortion in October 2017 and has been providing medication abortion using the FDA-approved, evidence-based mifepristone/misoprostol regimen ever since.

17. While WWH of Charlottesville currently has physicians providing all of its abortion care, it is actively recruiting advanced practice clinicians to join its staff to provide abortion care.

18. WWHA sues on its own behalf, on behalf of its current and future clinicians and staff, and on behalf of its patients.

[3] Consistent with standard medical practice, gestational ages as used in this complaint are dated from the first day of the patient's last menstrual period ("LMP"), which is typically approximately two weeks before the estimated date of fertilization of a pregnancy.

Whole Woman's Health

19. Plaintiff Whole Woman's Health ("WWH") operates a licensed healthcare facility in Alexandria, Virginia ("WWH of Alexandria") that provides abortion services up to 16 weeks LMP, including medication abortion up to 11 weeks LMP, and miscarriage management. WWH of Alexandria originally opened in 2019 under the name Whole Woman's Health and Family Center and began using the d/b/a name Whole Woman's Health of Alexandria in 2022. Since opening, it has provided medication abortion using the FDA-approved mifepristone/misoprostol regimen.

20. WWH of Alexandria currently has a nurse practitioner on staff who provides medication abortion to patients in-clinic.

21. WWH sues on its own behalf, on behalf of its current and future clinicians and staff, and on behalf of its patients.

Whole Woman's Health of the Twin Cities, LLC

22. Plaintiff Whole Woman's Health of the Twin Cities, LLC ("WWH of the Twin Cities") has operated a virtual healthcare program since August of 2021 that provides telehealth services for medication abortion in Virginia, Maryland, Minnesota, New Mexico, and Illinois. WWH of the Twin Cities provides telehealth medication abortion services up to 11 weeks LMP using the FDA-approved mifepristone/misoprostol regimen to approximately 2,400 patients per year, the majority of whom are in Virginia.

23. As part of its telehealth abortion services, WWH of the Twin Cities provides medication abortion to patients in Virginia via direct to patient telehealth. For this service, a provider meets with a patient via a telehealth visit, confirms that the patient is eligible for medication abortion, and obtains informed consent. The medications are then mailed to the patient.

24. While WWH of the Twin Cities currently has physicians providing all of its abortion care, it would like to hire advanced practice clinicians to work in its telehealth program.

25. WWH of the Twin Cities sues on its own behalf, on behalf of its current and future clinicians and staff, and on behalf of its patients.

Blue Mountain Clinic

26. Plaintiff Blue Mountain Clinic ("Blue Mountain") is a family practice in Missoula, Montana. It first opened in 1977 as the first and only abortion clinic in the state of Montana. In 1991, Blue Mountain expanded its health services to include comprehensive family medical care to better serve its community. Blue Mountain serves over 3,000 patients annually. It provides care across the lifespan, from pediatric care to elder care, including wellness exams, contraception, abortion care, and gynecological care. Blue Mountain provides medication abortion (in person and via telehealth) up to 11 weeks LMP and procedural abortions up to 21.6 weeks LMP, along with miscarriage management.

27. Blue Mountain's primary physician and its two physician assistants provide medication abortion using the FDA-approved, evidence-based mifepristone/misoprostol regimen. Blue Mountain also provides direct to patient telehealth, in which a provider meets with a patient via a telehealth visit, confirms that the patient is eligible for medication abortion, and obtains informed consent. The medications are then mailed to the patient at a Montana address.

28. Blue Mountain sues on its own behalf, on behalf of its current and future clinicians and staff, and on behalf of its patients.

Helen Weems and All Families Healthcare

29. Plaintiff Helen Weems is a certified nurse practitioner licensed to practice in Montana with over 20 years of clinical experience. She owns All Families Healthcare and is its

sole clinician and sole certified mifepristone prescriber. She is also the sole provider of abortion care in Montana's Flathead Valley.

30. Ms. Weems sues on her own behalf and on behalf of her patients.

31. Plaintiff All Families Healthcare is a sexual and reproductive health clinic in Whitefish, Montana, that provides LGBTQ+ care and gender-affirming care for transgender people, gynecological exams, diagnosis and treatment of sexually transmitted infections, contraception, and abortion care. All Families has been serving the Flathead Valley and patients across the entire state of Montana and beyond since it opened in 2018 and serves approximately 600 patients each year. All Families provides medication abortion (in person and via telehealth) up to 11 weeks LMP and procedural abortion up to 12.6 weeks LMP, along with miscarriage management. All Families provides medication abortion by direct to patient telehealth.

32. All Families sues on its own behalf, on behalf of its current and future clinicians and staff, and on behalf of its patients.

Trust Women

33. Plaintiff Trust Women operates clinics in Wichita, Kansas, and Oklahoma City, Oklahoma. Its mission is to provide essential and compassionate care to underserved populations. In Wichita, Kansas, Trust Women provides reproductive healthcare, including both procedural and medication abortion. Trust Women has provided medication abortion since it opened its Wichita clinic in 2013.

34. Trust Women Wichita provides medication abortion up to 11 weeks LMP using the mifepristone/misoprostol regimen, as well as procedural abortion up to 21.6 weeks LMP and miscarriage management.

35. Until 2018, Trust Women Wichita offered a telemedicine clinic for medication abortion, but was forced to stop that practice due to a Kansas state law. That law is now enjoined, and Trust Women Wichita is eager to restart its telemedicine clinic, including implementing direct to patient telehealth provision of mifepristone. But Trust Women Wichita has paused these plans given the cloud of uncertainty over mifepristone.

36. Trust Women sues on its own behalf, on behalf of its current and future clinicians and staff, and on behalf of its patients.

II. Defendants

FDA

37. Defendant FDA is an agency of the federal government within HHS. FDA is responsible for administering the provisions of the federal Food, Drug, and Cosmetic Act ("FDCA") that are relevant to this Complaint.

38. Defendant Robert M. Califf, M.D., is the Commissioner of FDA and is sued in his official capacity. He is responsible for administering FDA and its duties under the FDCA.

HHS

39. Defendant HHS is a federal agency within the executive branch of the federal government.

40. Defendant Xavier Becerra is the Secretary of HHS and is sued in his official capacity. He is responsible for the overall operations of HHS, including FDA.

ALLEGATIONS

I. FDA Has Repeatedly and Correctly Concluded that Mifepristone is Safe and Effective

41. In September 2000, FDA first approved mifepristone under the brand name Mifeprex,[4] developed by Danco Laboratories, to be used with the already approved drug misoprostol in the two-drug regimen: (1) mifepristone, which interrupts early pregnancy by blocking the effect of progesterone, a hormone necessary to maintain a pregnancy, and (2) misoprostol, which causes uterine contractions that expel the pregnancy from the uterus. Shortly after taking mifepristone and then misoprostol, a patient will experience bleeding akin to a heavy period or a miscarriage.[5]

42. To date, mifepristone has been used by over five million Americans.

43. FDA's initial approval of mifepristone was the result of a thorough, nearly five-year scientific review that determined mifepristone was safe for widespread use in the United States.

44. Mifepristone had already been approved in multiple countries across the world before being approved for use in the United States, and FDA reviewed extensive evidence from those countries.[6] Specifically, FDA reviewed: (1) three clinical trials that together involved 4,000 women—two French trials that were complete at the time of the application, and one then-ongoing United States trial for which summary data on serious adverse events was available;[7] (2) results

[4] U.S. Food & Drug Admin., NDA 20-687 Mifeprex Approval Memo, Sept. 28, 2000, attached hereto as Ex. A.

[5] *See* U.S. Gov't Accountability Office, GAO-08-751, Food and Drug Administration Approval and Oversight of the Drug Mifeprex (2008), https://www.gao.gov/assets/gao-08-751.pdf (hereinafter FDA Approval and Oversight of Mifeprex), attached hereto as Ex. B.

[6] U.S. Food & Drug Admin., Medical Officer's Review of NDA 20-687, at 2 (Nov. 1999), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2000/20687_Mifepristone_medr_P1.pdf, attached hereto as Ex. C; *see also* Laura Schummers et al., *Abortion Safety and Use with Normally Prescribed Mifepristone in Canada*, 386 New Eng. J. Med. 57 (2022).

[7] Ex. B (FDA Approval and Oversight of Mifeprex) at 15.

from other European data, including a database of approximately 415,000 women who received the mifepristone/misoprostol regimen;[8] and (3) data on the drug's manufacturing and chemistry.[9]

45. Based on its extensive review, in 2000, FDA concluded that there is "substantial evidence that Mifeprex is safe and effective for its approved indication in accordance with [the FDCA]"[10] and that mifepristone was safe for use in the United States.

46. In 2016, a multidisciplinary FDA review team conducted a medical review based on the 2.5 million uses of Mifeprex for medication abortion in the U.S. that had occurred since the drug's 2000 approval.

47. FDA updated the label for Mifeprex in 2016 to reflect the mounting research supporting the safety and efficacy of mifepristone.

48. Overall, in the 2016 review, FDA concluded: "[Mifeprex] has been increasingly used as its efficacy and safety have become well-established by both research and experience," "serious complications have proven to be extremely rare," "no new safety concerns have arisen in recent years," and "known serious risks occur rarely."[11]

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[8] U.S. Food & Drug Admin., FDA-2002-P-0364-0002, Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Donna Harrison, Exec. Dir., Am. Assoc. of Pro Life Obstetricians & Gynecologists, Gene Rudd, Senior Vice President, Christian Med. & Dental Ass'n, and Penny Young Nance, CEO and President, Concerned Women for Am., denying Citizen Petition, Docket No. FDA-2002-P0364, at 8 (Mar. 29, 2016) (hereinafter Citizen Petition Denial) attached hereto as Ex. D.

[9] Ex. B (FDA Approval and Oversight of Mifeprex) at 15.

[10] Ex. D (Citizen Petition Denial) at 8.

[11] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 020687Orig1s020, Mifeprex Medical Review(s) 8, 12 (Mar. 29, 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020MedR.pdf (hereinafter FDA 2016 Medical Review), attached hereto as Ex. E; *see also* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Full Prescribing Information for Mifeprex 7–8, tbls.1 & 2 (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/label/2016/020687s020lbl.pdf ("Mifeprex Labeling"), attached hereto as Ex. F.

49. FDA has further stated: "[t]he safety profile of Mifeprex is well-characterized and its risks well-understood after more than 15 years of marketing. Serious adverse events are rare and the safety profile of Mifeprex has not substantially changed."[12]

50. Still further, FDA has stated that "[g]iven that the numbers of . . . adverse events appear to be stable or decreased over time, it is likely that . . . serious adverse events will remain acceptably low" for Mifeprex.[13]

51. In reaching those conclusions, FDA relied on no fewer than 11 independent clinical studies, collectively representing "well over 30,000 patients," and conclusively showing "serious adverse events" at rates "generally far below 1.0%."[14]

52. The 2016 review cited a host of studies showing that the rate of major adverse events was roughly 0.3%, with multiple studies reporting even lower rates of infection (such as 0%, 0.014%, and 0.015%).[15] *Hundreds* of additional high-quality studies conducted since mifepristone's 2000 approval show the same. Mifepristone has been used in over 600 published clinical trials and discussed in nearly 800 medical reviews.[16]

53. FDA determined that at-home administration of misoprostol is safe because multiple studies showed that administration of the drug was "associated with exceedingly low rates of serious adverse events" and because administering misoprostol at home would more likely result

[12] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s): REMS Modification Memorandum 3 (Mar. 29, 2016) (hereinafter 2016 REMS Modification Memorandum), attached hereto as Ex. G.

[13] Ex. E (FDA 2016 Medical Review) at 47.

[14] *Id.* at 50, 56.

[15] *Id.* at 54, 56.

[16] Based on a review of publications on PubMed. *See generally* PubMed, Nat'l Library of Med., https://pubmed.ncbi.nlm.nih.gov/?term=mifepristone (last visited Apr. 27, 2023).

in patients being in an "appropriate and safe location" when cramping and bleeding caused by the drug would begin.[17]

54. FDA's 2016 review further concluded that the risk of death from mifepristone is near zero. The FDA review reflected that there are only 13 recorded deaths even possibly related to medication abortion—roughly 0.00000232%—and none of these can be causally attributed to mifepristone.[18] In either case, that is far less than the risk of death from the use of Viagra[19] or over-the-counter medications such as acetaminophen.[20]

55. FDA further noted that, as to rare, serious infections following use, "the critical risk factor" is not mifepristone but "pregnancy itself," as the very same complications can arise during a miscarriage or procedural abortion.[21]

56. In updating the Mifeprex label in 2016, FDA stated: "serious and potentially life-threatening bleeding, infections, or other problems can occur following a miscarriage, surgical abortion, medical abortion, or childbirth" and that "[n]o causal relationship between the use of MIFEPREX and misoprostol and [infections and bleeding] has been established."[22]

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[17] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 020687Orig1s020, Mifeprex Summary Review 15 (Mar. 29, 2016) (hereinafter 2016 Summary Review), attached hereto as Ex. H.

[18] U.S. Food & Drug Admin., Mifepristone U.S. Post-Marketing Adverse Events Summary through 06/30/2022, at 1, https://www.fda.gov/media/164331/download (hereinafter Mifepristone U.S. Post-Marketing Adverse Events Summary), attached hereto as Ex. I (concluding that there are 28 reported deaths total, which are included in the adverse events summary "regardless of causal attribution to mifepristone," and these cases include instances of homicide, drug overdose, ruptured ectopic pregnancy, and sepsis.)

[19] Mike Mitka, *Some Men Who Take Viagra Die—Why?*, 283 JAMA Network 590 (Feb. 2, 2000) (Viagra associated with 4.9 deaths per 100,000 prescriptions).

[20] Nat'l Acads. of Sci., Eng'g. & Med., *The Safety and Quality of Abortion Care in the United States* 79 (2018) (hereinafter National Academies Report), http://nap.edu/24950; Suneil Agrawai & Babek Khazaeni, *Acetaminophen Toxicity*, Nat'l Library of Med. (Feb. 12, 2023), https://www.ncbi.nlm.nih.gov/books/NBK441917.

[21] Ex. D (Citizen Petition Denial) at 25 n.69.

[22] Ex. F (Mifeprex Labeling) at 2, 16.

57. FDA found that mifepristone was just as safe when administered by an advanced practice clinician as it was when administered by a physician, noting that "5 studies clearly demonstrate[] that efficacy is the same with non-physician providers compared to physicians."[23]

58. FDA also found no significant difference in outcomes based on whether patients had follow-up appointments via phone call or in-person or based on the timing of those appointments.

59. Relying on the updated safety data and efficacy it had collected for mifepristone, FDA made several changes to the REMS, including allowing a broader set of healthcare providers, rather than only physicians, to become certified prescribers of mifepristone, and several changes to the labeling, including increasing the indicated gestational limit from 49 to 70 days and reducing the indicated number of in-person clinic visits to one.[24]

60. In 2019, FDA approved an abbreviated new drug application for a generic version of mifepristone from GenBioPro, relying on the extensive safety and efficacy determinations made in connection with Danco's Mifeprex.

61. In July 2020, a court ordered FDA to suspend the in-person dispensing requirement for mifepristone due to the constraints on in-person healthcare during the COVID-19 pandemic. *Am. Coll. of Obstetricians & Gynecologists v. FDA*, 472 F. Supp. 3d 183, 233 (D. Md. 2020), *stayed by FDA v. Am. Coll. of Obstetricians & Gynecologists*, 141 S. Ct. 578, 578 (2021) (mem.).

62. In April 2021, FDA itself suspended the in-person dispensing requirement during the COVID-19 public health emergency because, during the six-month period in which the in-

[23] Ex. E (FDA 2016 Medical Review) at 43.

[24] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 020687Orig1s020, Mifeprex REMS (Mar. 2016), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2016/020687Orig1s020RemsR.pdf (hereinafter 2016 REMS).

person dispensing requirement had been enjoined, the availability of direct to patient telehealth showed no increases in serious patient safety concerns.[25]

63. On January 3, 2023, FDA removed the in-person dispensing requirement permanently due to the proven safety record of dispensing mifepristone through direct to patient telehealth.[26]

64. Finally, when the safety of mifepristone was called into question by anti-abortion activists in a lawsuit filed in November 2022, FDA defended its approval of mifepristone by repeatedly emphasizing its proven safety record over the last 23 years, comparing its risk to that of ibuprofen. Emergency Mot. Under Cir. R. 27.3 for a Stay Pending Appeal at 1, 14–15, *All. for Hippocratic Med. V. FDA*, No. 23-10362 (5th Cir. Apr. 10, 2023).

65. FDA's analysis of mifepristone's safety has been echoed by other leading medical organizations. In 2018, the National Academies of Sciences, Engineering, and Medicine ("National Academies"), a universally respected non-partisan advisory institution, reviewed all available scientific evidence and concluded that the risks of medication abortion are "similar in magnitude to the reported risks of serious adverse effects of commonly used prescription and over-the-counter medications," such as "antibiotics and NSAIDS"[27] (non-steroidal anti-inflammatory drugs, such as ibuprofen and aspirin)—medications millions of people take daily.[28] This massive body of

[25] Letter from Janet Woodcock, Acting Comm'r, U.S. Food & Drug Admin., to Maureen G. Phipps, Chief Exec. Officer, Am. Coll. Of Obstetricians & Gynecologists, and William Grobman, President, Soc'y for Maternal-Fetal Med. (Apr. 12, 2021) (hereinafter Woodcock Letter), attached hereto as Ex. J.

[26] *See* U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., Risk Evaluation and Mitigation Strategy (REMS) Single Shared System for Mifepristone 200 MG (Jan. 2023), https://www.accessdata.fda.gov/drugsatfda_docs/rems/Mifepristone_2023_01_03_REMS_Full.pdf (hereinafter 2023 REMS).

[27] National Academies Report, *supra* n.20, at 45, 79.

[28] Pamela Gorczyca et al., *NSAIDs: Balancing the Risks and Benefits*, 41 U.S. Pharmacist 24 (Mar. 2016), http://bit.ly/3YLbw3x.

evidence has shown that mifepristone is safer than many other common drugs, including Viagra and penicillin, and over-the-counter drugs like Advil and Tylenol. This evidence has specifically shown that mifepristone is safe and effective when provided without an in-person visit, by advanced practice clinicians, and through 11 weeks of pregnancy.

II. Mifepristone is Essential Medication for People's Health and Wellbeing

66. People end their pregnancies with medication or by procedure. Many people seek medication abortion with mifepristone because it can be easier to access, particularly for patients in communities facing the most obstacles to care, including Black, Indigenous, and other people of color, those with low incomes, LGBTQ+ people, young people, immigrants, people with disabilities, and those living at the intersection of those identities.

67. Medication abortion actively reduces what may be insurmountable barriers people face in accessing abortion care. People commonly take mifepristone at home following a consultation with a healthcare provider because they can have an abortion in privacy, at a place of their choosing, and with the support of their immediate network.[29] And it allows people to forgo the physical contact and vaginal insertions of a procedural abortion, which may be particularly important for survivors of sexual violence and people experiencing gender dysphoria.

68. Having an abortion at home also can benefit both patients and providers. Telehealth, including direct to patient telehealth, can eliminate the exposure risks inherent in in-person clinic visits, particularly in light of the persistent and escalating violence and harassment at clinics known

[29] *See* Charlotte Kanstrup et al., *Women's Reasons for Choosing Abortion Method: A Systematic Literature Review*, 46 Scandinavian J. Pub. Health 835 (2018); Pak Chung Ho, *Women's Perceptions on Medical Abortion*, 74 Contraception 11 (2006).

to provide abortion.[30] It can also reduce wait times[31] and remove barriers to healthcare due to travel costs.[32] For people with disabilities and others for whom travel is difficult, the use of local and mail-order pharmacies significantly increases the accessibility of medication abortion.[33]

69. These concerns are neither abstract nor insignificant for someone who is pregnant. Each day a person remains pregnant means they continue to experience the symptoms, risks, and potential complications of pregnancy. Pregnancy—even when uncomplicated—stresses the body, causes physiological and anatomical changes, and affects every organ system.

70. Pregnancy can also worsen underlying health conditions, many of which are common, such as diabetes and hypertension. Other conditions can develop simply because a person is pregnant, including gestational diabetes, gestational hypertension (including preeclampsia), and hyperemesis gravidarum—a condition that causes severe nausea and vomiting. For people who continue their pregnancies and give birth, health conditions such as hypertension and diabetes can contribute to preterm birth.

71. People who continue their pregnancies and give birth face significant risk in the United States—in large part as a result of systemic discrimination and inequitable access to healthcare. Every pregnancy-related complication is more common among people having live

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[30] *See* Press Release, Nat'l Abortion Fed'n, *National Abortion Federation Releases 2021 Violence & Disruption Report* (June 24, 2022), https://prochoice.org/national-abortion-federation-releases-2021-violence-disruption-report (reporting steady increase in harassment and violence at abortion clinics over 45-year period); U.S. Dep't of Just., *Recent Cases on Violence Against Reproductive Health Care Providers* (Oct. 18, 2022), https://www.justice.gov/crt/recent-cases-violence-against-reproductive-health-care-providers.

[31] Liam Caffery, Mutaz Farjian & Anthony C. Smith, *Telehealth Interventions for Reducing Waiting Lists and Waiting Times for Specialist Outpatient Services: A Scoping Review*, 22 J. Telemed. & Telecare 504 (2016).

[32] Abid Haleem et al., *Telemedicine for Healthcare: Capabilities, Features, Barriers, and Applications*, 2 Sensors Int'l 100117 (2021).

[33] *See, e.g.*, Allison M. Whelan & Michele Goodwin, *Abortion Rights and Disability Equality: A New Constitutional Battleground*, 79 Wash. & Lee L. Rev. 965, 989–90, 996–97 (2022).

births than among those having abortions. Vaginal delivery can result in trauma to the pelvic floor and other significant injury. And, for the approximately one-third of pregnancies ending in a caesarean section (C-section), patients will undergo a major abdominal surgery that carries risks of infection, hemorrhage, and damage to internal organs. Pregnancy also has potentially long-term physical, emotional, and mental effects on a person who goes through childbirth, sometimes persisting well after birth.

72. Forced pregnancy and childbearing also have long-term impacts on a person's educational and economic futures, and their ability to shape their lives. People who are denied a wanted abortion are more likely to experience economic insecurity and raise their existing children in poverty. The financial impacts of being denied an abortion are as large as or larger than being evicted, losing health insurance, or being hospitalized.[34]

73. The likelihood of being denied abortion care has grown exponentially since the U.S. Supreme Court overruled *Roe* nearly one year ago. Thirteen states have banned abortion, and several others have severely restricted access to this basic, yet critical, care. In the states where abortion remains legal, and even protected, it is subject to restrictions not imposed on equally safe or more dangerous interventions. The persistence of a unique set of federal restrictions on mifepristone is part of the same set of efforts to put safe, effective options for pregnancy care out of reach.

74. Medication abortion has become an increasingly critical method on which patients and clinics rely in the face of an ongoing reproductive healthcare crisis; it makes up over half the abortion care provided in the country. Service-delivery advancements, like providing medication

[34] Diana G. Foster et. al., *Socioeconomic Outcomes of Women Who Receive and Women Who Are Denied Wanted Abortions in the United States*, 108 Am. J. Pub. Health 407 (Mar. 2018); Sarah Miller, Laura R. Wherry & Diana G. Foster, *The Economic Consequences of Being Denied an Abortion*, 15 Am. Econ. J.: Econ. Pol'y 394 (Feb. 2023).

abortion via direct to patient telehealth, moderate the strain on the ever-shrinking number of clinics struggling to provide care for a dramatic increase in patients.[35] Dozens of clinics have closed or stopped offering abortion care since the U.S. Supreme Court overruled *Roe*.[36] Currently, roughly 10 percent of U.S. counties have an abortion provider that offers either procedural or medication abortion (or both); in roughly 2 percent of U.S. counties, the only option is medication abortion.[37]

75. For people who remain pregnant—or need care at some point during a pregnancy—there are also dwindling options. Counties in more than one-third of the country are maternity care deserts, without obstetric providers, birth centers, or labor and delivery hospitals.[38] Federal law requires Medicaid, which covers 4 births in 10 each year—and even more for people of color and people in rural areas—to provide pregnancy-related coverage through only 60 days postpartum, disenrolling people just 2 months after birth, when consistent coverage remains critical. States may provide additional coverage, but must take additional steps to implement that extension.

76. The United States has one of the highest maternal mortality rates among wealthy democracies. According to recent Centers for Disease Control and Prevention reports, the maternal mortality rate has risen since 2018.[39] This human rights crisis in U.S. maternal health

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[35] *See* Caitlin Myers et al., *Abortion Access Dashboard* (last updated Mar. 23, 2023), https://experience.arcgis.com/experience/6e360741bfd84db79d5db774a1147815/page/Page/?views=March-2023 (noting that there has been a 32% increase in women per abortion facility since March 1, 2022).

[36] Marielle Kirstein et al., *100 Days Post-Roe: At Least 66 Clinics Across 15 US States Have Stopped Offering Abortion Care*, Guttmacher Inst. (Oct. 6, 2022), https://www.guttmacher.org/2022/10/100-days-post-roe-least-66-clinics-across-15-us-states-have-stopped-offering-abortion-care.

[37] Jesse Philbin et al., *10 US States Would Be Hit Especially Hard by a Nationwide Ban on Medication Abortion Using Mifepristone*, Guttmacher Inst. (Feb. 7, 2023), https://www.guttmacher.org/2023/02/10-us-states-would-be-hit-especially-hard-nationwide-ban-medication-abortion-using.

[38] Christina Brigance et al., March of Dimes, *Nowhere to Go: Maternity Deserts Across the U.S.* 5 (2022), https://www.marchofdimes.org/sites/default/files/2022-10/2022_Maternity_Care_Report.pdf.

[39] Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2021*, Centers for Disease Control and Prevention National Center for Health Statistics (Mar. 2023), https://www.cdc.gov/nchs/data/hestat/maternal-

disproportionately impacts Black, Indigenous, and low-income communities, who consistently face the greatest risks during pregnancy, childbirth, and postpartum due to racism, discrimination, and inadequate access to quality health services. As a result, Black women are three to four times more likely to die of a pregnancy-related death in the United States, and Indigenous women are 2.3 times more likely than white women.[40] As the National Academies summarizes, as a result of systemic racism, including inequitable treatment and distribution of resources, "women of color enter into their reproductive lives, and ultimately their pregnancies, at risk for adverse pregnancy outcomes."[41] Pregnancy "represents a dangerous time for disabled and nondisabled persons alike in the United States" given the country's high maternal mortality rate, and while "[m]ost persons with disabilities can safely carry pregnancies to term . . . some may face a higher risk of complications, rendering pregnancy dangerous or even life-threatening."[42]

77. Bringing a child into the world, raising children, and building families and communities are, for many, among the most joyful and meaningful experiences in life. At the same time, these life-changing events bring challenges and risks, as evidence well documents. The ability to make decisions about whether to continue or end a pregnancy, and by what method, is critical to a person's dignity and autonomy. Continued enforcement of the REMS perpetuates

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mortality/2021/maternal-mortality-rates-2021.pdf (citing maternal mortality rate of 20.1 in 2019, 23.8 in 2020, and 32.9 in 2021); Donna L. Hoyert, *Maternal Mortality Rates in the United States, 2019*, Centers for Disease Control and Prevention National Center for Health Statistics (Apr. 2021), https://www.cdc.gov/nchs/data/hestat/maternal-mortality-2021/E-Stat-Maternal-Mortality-Rates-H.pdf (describing maternal mortality rate of 20.1 in 2019 as "significantly higher than the rate for 2018," which was 17.4).

[40] Emily E. Petersen, et al., *Racial/Ethnic Disparities in Pregnancy-Related Deaths—United States, 2007-2016*, Centers for Disease Control and Prevention Morbidity and Mortality Weekly Report (Sept. 6, 2019), https://www.cdc.gov/mmwr/volumes/68/wr/mm6835a3.htm?s_cid=mm6835a3_w#T1_down.

[41] *See* Nat'l Acads. of Sci., Eng. & Med., *Birth Settings in America: Outcomes, Quality, Access, and Choice* 122 (2020), https://nap.nationalacademies.org/download/25636#.

[42] Whelan & Goodwin, *supra* n.33, at 997.

harmful and unnecessary barriers that make it more difficult to access essential healthcare and interferes with this decision-making.

III. Despite Acknowledging its Safety, FDA Has Continued to Saddle Mifepristone with the REMS, A Uniquely Burdensome Regulatory Scheme

78. From the very beginning, FDA has overregulated mifepristone in ways that are unjustified and discriminatory. But even as decades of data has accumulated showing mifepristone to be one of the safest medications available in the United States, FDA has continued to subject mifepristone to uniquely burdensome restrictions with increasingly little reason for doing so. These restrictions are already irrational, but in light of the recent chaos surrounding mifepristone, they have also become intolerable and incompatible with Plaintiffs' ability to meet the needs of their patients.

79. Under the FDCA, a new drug must undergo a rigorous examination to determine its safety and efficacy. *See generally* 21 U.S.C. § 355. For all prescription drugs, FDA ensures that certain safeguards are in place before it approves a medication. As part of this process, FDA may impose specific warnings, indications, and instructions.

80. A "Risk Evaluation and Mitigation Strategy" ("REMS") is an unusual overlay of requirements, far outside of the norm, that FDA can choose to impose only when "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1).

81. The most burdensome type of REMS is "Elements to Assure Safe Use" ("ETASU"), which FDA imposes only if medically necessary due to a drug's "inherent toxicity or potential harmfulness." 21 U.S.C. § 355-1(f)(1). By statute, ETASU is only appropriate for drugs with serious side effects such as death, incapacity, or birth defects, and only where the risk of side effects is sufficiently severe that the drug requires ETASU for safe use. 21 U.S.C. §§ 355-1(b)(4), (f)(1)(A).

82. REMS, and in particular REMS with ETASU, are extremely unusual: only 60 REMS programs are in place, 56 of which include ETASU, among the more than 20,000 prescription drug products approved by FDA and marketed in the U.S. Other than mifepristone, the drugs with ETASU are dangerous drugs like fentanyl and other opioids.

83. Over the years, FDA has imposed numerous requirements on mifepristone through the REMS and ETASU, including:

- An in-person dispensing requirement (or ban on direct to patient telehealth) (21 U.S.C. § 355-1(f)(3)(C)) that provided mifepristone be dispensed only in a clinic, medical office, or hospital by or under the supervision of a "certified provider," who until 2016 could only be a physician. As a result, people could not access mifepristone by prescription from a brick-and-mortar or mail-order pharmacy. This requirement was temporarily suspended in 2021 and permanently removed in 2023, enabling patients to access medication abortion by mail and opening the door for brick-and-mortar pharmacies to dispense mifepristone. Although it removed the in-person dispensing requirement, FDA imposed a mandate that pharmacies, like prescribers, be "certified."
- A Prescriber Certification requirement (21 U.S.C. § 355-1(f)(3)(A)), which mandated that clinicians who prescribe mifepristone attest to their clinical abilities in a signed form kept on file by the manufacturer, and agree to comply with reporting and other REMS requirements.
    - Before 2016, only physicians could be certified mifepristone prescribers, although advanced practice clinicians (nurse practitioners, nurse midwives, and physician assistants) could provide mifepristone under the supervision of a physician.

- The certified prescriber requirement remains under the January 2023 REMS, but, in 2016, FDA expanded who could be a certified prescriber to include other clinicians, such as advanced practice clinicians.

- A Patient Agreement requirement (21 U.S.C. § 355-1(f)(3)(D)), mandating the prescriber and patient to review and sign a special form with information about the mifepristone regimen and risks, and requiring the prescriber to provide the patient with a copy and place a copy in the patient's medical record. The same information contained in the patient form is also included in the "Medication Guide" that is part of the FDA-approved labeling provided to patients with mifepristone. This requirement remains part of the 2023 REMS.

84. None of these requirements were justified at any time in light of FDA's repeated determination about the safety and efficacy of mifepristone.

IV. Over the Pleas of the Medical Community that Each Iteration of the REMS is Medically Baseless and Harms Patients and Providers, FDA has Maintained a REMS on Mifepristone for No Valid Reason

85. FDA reevaluated the provisions of the mifepristone REMS in 2016, and again in 2019, 2021, and 2023, but it has continually decided to reimpose the REMS despite longstanding objections from the medical community and its own review of the data showing mifepristone's safety and efficacy.

86. During FDA's 2016 review of the REMS, dozens of medical experts and their organizations asked FDA to eliminate the REMS because of the harms it imposed on patients and providers without any medical benefit. Among those groups were the preeminent medical professional organizations in the United States, including the American College of Obstetricians and Gynecologists (ACOG), the American Public Health Association (APHA), and the Society of Family Planning (SFP).

87. As one letter, signed by 30 organizational experts in reproductive rights and health, advanced: "[a]lthough the FDA may have decided 15 years ago that the balance of risk and burden came out in favor of restricting mifepristone's indicated use and distribution, today both science and the current conditions surrounding patient access to abortion care call strongly for a reevaluation of the mifepristone label and REMS restrictions, especially its Elements to Assure Safe Use (ETASU)."[43]

88. The letter further urged FDA to "[c]onsider the current legal and social climate," explaining that "[t]he overall legal and social climate around abortion care intensifies all of the burdens that the mifepristone REMS places on patients and makes it even more critical that the FDA lift medically unnecessary restrictions on the drug."[44] The letter concludes:

> Mifepristone continues to hold immense promise for patient access to a safe and effective early abortion option, but medically unnecessary regulations are impeding its full potential. Extensive scientific and clinical evidence of mifepristone's safety and efficacy, and the ever-increasing burden on patient access to abortion care, clearly demonstrate that mifepristone's REMS program is not needed to protect patients. In light of the FDA's statutory mandate from Congress to consider the burden caused to patients by REMS, and the agency's own stated commitment to ensuring that the drug restrictions do not unduly burden patient access, we ask that the FDA lift mifepristone's REMS . . . .[45]

89. In addition to requesting that FDA remove the REMS entirely, the letter made specific requests about several particularly baseless aspects of the REMS.

90. Specifically, the letter requested that FDA remove the restriction preventing advanced practice clinicians from becoming certified prescribers of Mifeprex. It stated that this

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[43] Letter from Soc'y of Fam. Plan. et al., to Stephen Ostroff, Acting Comm'r of Food & Drugs, Robert M. Califf, Deputy Comm'r for Med. Prods. & Tobacco & Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin. 2 (Feb. 4, 2016) (hereinafter SFP Letter to FDA), attached hereto as Ex. K.

[44] *Id.* at 5.

[45] *Id.* at 6.

limitation was "medically unnecessary and severely limits patients' access to medication abortion care."[46]

91. FDA modified the certified prescriber requirement, eliminating language that a certified prescriber had to be a physician, and instead providing that a healthcare provider may prescribe mifepristone so long as doing so is consistent with their state licensure.[47]

92. The letter also requested the removal of the requirement that mifepristone only be dispensed in clinics, medical offices, or hospitals—effectively banning it from being dispensed by direct to patient telehealth. In addition to the fact that it was "not medically warranted," the letter stated, the "requirement significantly curtails mifepristone's potential to expand patient access to abortion care," which is "especially significant in underserved and rural areas where access to a health care provider is already difficult, and for those with low incomes for whom taking off work or getting to a provider multiple times in short order is impossible due to cost or family needs."[48]

93. FDA decided to retain the in-person dispensing requirement in 2016, citing no medical risks associated with direct to patient telehealth, and stating in a conclusory fashion that this requirement ensures mifepristone is dispensed by or under the supervision of a certified prescriber.[49]

94. In 2021, FDA temporarily suspended the in-person dispensing requirement during the COVID-19 public health emergency, citing a review of studies demonstrating no increase in

[46] *Id.* at 4.

[47] *See* Ex. E (FDA 2016 Medical Review) at 79–80.

[48] Ex. K (SFP Letter to FDA) at 2.

[49] Ex. E (FDA 2016 Medical Review) at 89.

serious safety concerns with this change.[50] FDA also noted that requiring patients to make in-person visits to a clinic solely to access mifepristone could "present additional COVID-related risks to patients and healthcare personnel."[51]

95. And, based on a 2021 review, FDA permanently removed the in-person dispensing requirement in January 2023, concluding that available data and information supported this modification to the REMS "to reduce burden on the health care delivery system and to ensure the benefits of the product outweigh the risks."[52] FDA, however, imposed a requirement that, like prescribers, pharmacies that dispense mifepristone be specially certified.[53]

96. In 2016, the experts further asked FDA to: (1) "[e]liminate the Prescriber Agreement certification requirement" and (2) "[r]emove the confusing and unnecessary Patient Agreement."[54] Neither requirement was necessary for the safe distribution of mifepristone—especially considering the "many laws, policies, and ordinary standards of practice" to which health professionals are subject.[55] The requirements also did not apply to drugs that carry more risk than mifepristone.[56] The experts argued that the Patient Agreement "should be eliminated entirely" as it was "medically unnecessary and interferes with the clinician-patient relationship."[57]

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[50] Ex. J (Woodcock Letter) at 1–2.

[51] *Id.* at 2.

[52] U.S. Food & Drug Admin., Information About Mifepristone for Medical Termination of Pregnancy Through 10 Weeks Gestation (Mar. 23, 2023), https://www.fda.gov/drugs/postmarket-drug-safety-information-patients-and-providers/information-about-mifepristone-medical-termination-pregnancy-through-ten-weeks-gestation.

[53] *Id*. ("To become certified to dispense mifepristone, pharmacies must complete a Pharmacy Agreement Form.")

[54] Ex. K (SFP Letter to FDA) at 3–4.

[55] *Id.* at 3.

[56] *Id*.

[57] *Id.* at 4.

97. The FDA expert review team unanimously recommended eliminating the Patient Agreement Form because it "contains duplicative information already provided by each healthcare provider or clinic," "does not add to safe use conditions," and "is a burden for patients."[58]

98. They were, however, overruled by the FDA Commissioner for no apparent reason.[59]

a. Reimposing the Pre-2016 REMS Would Gravely Harm Plaintiffs' Practices and Patients

99. The harms of *reimposing* those parts of the REMS eliminated in 2016 (parts that would be reinstated if the Fifth Circuit's decision in the *Alliance* Case takes effect in the Plaintiffs' states) are even greater than when FDA reviewed and removed these requirements initially—and exponentially so in the wake of the Supreme Court's overruling of *Roe* and half the country moving to ban or severely restrict abortion. And the mountain of evidence and experience demonstrating safety, efficacy, and patient satisfaction in the absence of these requirements has only grown.

100. *First*, reinstating the physician-only requirement for certified prescribers retracts the pool of qualified mifepristone providers. And it does so after years of incremental progress to build a network of advanced practice clinicians (including nurse practitioners, nurse midwives, and physician assistants) with the training and experience to provide this critical care. Indeed, since 2016, the number of states that permit clinicians other than physicians to provide abortion care has grown from 12 to 18.

[58] Ex. H (2016 Summary Review) at 25.

[59] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 020687Orig1s020, Mifeprex Risk Assessment and Risk Mitigation Review(s): Letter from Janet Woodcock, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., Re: NDA 020687, Supp 20, at 1 (Mar. 28, 2016) (hereinafter "Woodcock Patient Agreement Memo"), attached hereto as Ex. L.

101. Plaintiffs WWH, Blue Mountain, and All Families all employ advanced practice clinicians who provide abortion care. Trust Women would want to use advanced practice clinicians to mail mifepristone if they are ultimately able to start their telehealth program.

102. In the case of All Families, *the sole clinician prescribing and providing abortion is an advanced practice clinician*. Reinstating the REMS' physician-only requirement for certified prescribers will thus eliminate the sole mifepristone provider from the northwest region of Montana.

103. *Second*, reinstating the REMS requirement that mifepristone be dispensed only in a clinic, medical office, or hospital—and not via mail-order pharmacy—will eliminate abortion access for the large number of patients who have come to rely on direct to patient telehealth services, and destroy Plaintiffs' virtual care models for mifepristone. Plaintiffs WWH, Blue Mountain, and All Families have all devoted substantial time and effort to developing telehealth abortion services. Their patients, many of whom are in rural or underserved communities, depend on telehealth services to access abortion care, particularly post-*Roe*. Trust Women Wichita, which has experienced a huge surge in patients seeking care following the criminalization of abortion in neighboring states, is interested in starting a direct to patient telehealth program if able, and intended to develop a telemedicine program involving direct to patient provision of medication abortion when the present uncertainty around mifepristone began.

104. At a minimum, Plaintiffs must be able to rely on the 2023 REMS to be able to continue providing their patients with high-quality, evidence-based abortion care.

b. The 2023 REMS Also Gravely Harms Plaintiffs' Practices and Patients

105. Yet, even the 2023 REMS erects unnecessary barriers to mifepristone. Experts have repeatedly told FDA to abandon three primary hurdles to accessing mifepristone that continue to plague Plaintiffs and their patients. Each restricts mifepristone without any valid medical basis.

106. *First*, the 2023 REMS retains the Patient Agreement Requirement even though FDA experts unanimously recommended its abandonment in 2016. It requires a patient to certify: "I have decided to take mifepristone and misoprostol to end my pregnancy." It must be signed by both the patient and provider, a copy must be placed into the patient's medical record, and a copy must be given to the patient along with the Medication Guide.

107. This Patient Agreement Form risks the privacy of patients and providers by specifically identifying the patient as taking the medication for the purpose of ending their pregnancy—as opposed to, for instance, miscarriage management, for which the medication is also frequently prescribed.[60]

108. If someone obtains access to the patient's medical record—which is all the more possible with states criminalizing abortion and imposing civil liability for people assisting others in accessing abortion—they will have evidence that the patient received the medication for abortion. This is a particular concern for patients who travel from a state where abortion is banned to a state where it is legal.

109. Further, patients receiving mifepristone for miscarriage management must also sign the Patient Agreement Form, requiring them to make a false and potentially traumatizing attestation that they are "decid[ing]" to "end [their] pregnancy" when they are experiencing a pregnancy loss.

110. The form also identifies the provider to people who have access to the patient record, potentially including, for example, a patient's spouse, partner, or parent. This exposes providers and patients to threats of reprisal, especially in today's climate of hostility to abortion.

[60] *See, e.g.*, ACOG Practice Bulletin No. 200, Early Pregnancy Loss, e197, e203 (Nov. 2018, reaff'd 2021), https://www.acog.org/clinical/clinical-guidance/practice-bulletin/articles/2018/11/early-pregnancy-loss; *see also* Courtney A. Schreiber et al., *Mifepristone Pretreatment for the Medical Management of Early Pregnancy Loss*, 378 New Eng. J. Med. 2161 (2018).

111. There is no countervailing benefit in the face of these harms, as the information contained on the form is useless; it is duplicative of the information already provided to patients in the five-page Medication Guide that accompanies mifepristone. The comprehensive Medication Guide answers questions about symptoms, side effects, and eligibility, as does the provider when they counsel patients on the risks and benefits of treatment.

112. *Second*, the 2023 REMS retains the Certified Prescriber Requirement: mifepristone can only be prescribed by a healthcare provider who has undergone a "special[] certif[ication]" process. This "special certification" must be submitted to each certified pharmacy used by the provider and to the distributor if a provider intends to dispense in their office.

113. As plaintiffs in the Washington case attested, for many healthcare providers, "becoming specially certified is unduly burdensome and raises safety concerns." Compl. ¶ 97, *Washington v. FDA*, No. 1:23-CV-3026, 2023 WL 2223480 (E.D. Wash. Feb. 23, 2023). Some providers "are deterred by the unusual step of having to become certified to prescribe the medication; others, misled by mifepristone's REMS designation, misperceive it is a dangerous medication or out of the prescriber's scope of practice; and still others are not comfortable having their names compiled in a list of medication abortion prescribers for fear that they or their families may be targeted by anti-abortion activists." *Id.* This fear is particularly acute for clinicians who hold licenses in multiple states. *Id.*

114. These concerns, which FDA was made aware of as far back as 2016, are heightened now due to the growing criminalization and penalization of abortion, including laws that subject health care providers to criminal penalties and significant monetary liability. *Id.*

115. There is no reason that providers at Plaintiffs' clinics, who are not party to the Washington case, should have to be subject to these same risks from being certified prescribers.

Nor should they be subject to the instability about their status as certified prescribers—caused most recently by the current chaos and dueling court orders. The medically baseless certified prescriber requirement contributes to the stigma around abortion care and abortion providers that Plaintiffs experience, and it restricts the number of available clinicians who might be able to be certified prescribers at Plaintiffs' clinics to those who are willing to go through additional hurdles. Plaintiffs' patients should be able to access mifepristone from their trusted provider—whether it be the Plaintiff providers, or a primary care clinician in another practice.

116. *Finally*, the 2023 REMS imposes a Pharmacy Certification Requirement, which like for prescribers, mandates pharmacies be "specially certified" by the manufacturer. To certify, pharmacies must verify the status of "certified" providers and follow unnecessary and burdensome recordkeeping and training requirements not associated with any comparable medication. By limiting mifepristone dispensing to "certified" pharmacies, the REMS requires providers like Plaintiffs to track certified pharmacies, instead of allowing patients to decide from which pharmacy to pick up the medication, as they could do with numerous other prescription medications. Pharmacies, too, will have to track and confirm which prescribers are "certified" to ensure that, each time they seek to dispense mifepristone, they only dispense it to a patient whose prescription came from a certified prescriber.

117. As a practical matter, erecting this logistical "certification" barrier limits the number of pharmacies that dispense mifepristone, and thus limits access to mifepristone for Plaintiffs and their patients—just as the requirement that prescribers be certified has limited access to mifepristone. Although the 2023 REMS opens the door to allow brick-and-mortar pharmacies to dispense mifepristone, the mandate that they be certified may just as quickly shut that door.

118. Simply put, the 2023 REMS retains unnecessary and harmful dispensing and prescribing requirements that threaten patient and provider privacy and continue to put mifepristone out of reach despite its exemplary safety record. As one recent study of clinicians and administrators put it, although mifepristone is safe and effective, the REMS are the "linchpin of a cycle of stigmatization that continues to keep mifepristone out of primary care practice."[61]

119. FDA has tacitly acknowledged that mifepristone is subject to discriminatory restrictions. In 2012, FDA approved *without a REMS* a higher-dose mifepristone product—Korlym—as treatment for Cushing's syndrome. Patients prescribed Korlym take one to four 300 mg pills *daily*—which is 1.5 to 6 times the recommended dose of mifepristone used for abortion care, which typically involves only one 200 mg pill.[62] FDA concluded that "[a]ny restrictions will impede access with little to no benefit to Cushing's syndrome population" and that risks "can be adequately addressed through labeling," as with other drugs.[63] Indeed, FDA identified two drugs—misoprostol and methotrexate—associated with pregnancy termination which are regulated only through labeling, not a REMS.[64]

120. And, as the American Academy of Family Physicians has summarized, numerous "other drugs with higher complication rates, such as acetaminophen, aspirin, loratadine, and

[61] Danielle Calloway, Debra B. Stulberg & Elizabeth Janiak, *Mifepristone Restrictions and Primary Care: Breaking the Cycle of Stigma Through a Learning Collaborative Model in the United States*, 104 Contraception 24 (2021).

[62] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 202107Orig1s000, Full Prescribing Information for Korlym (mifepristone), at 3 (Feb. 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000Lbl.pdf.

[63] U.S. Food & Drug Admin., Ctr. for Drug Evaluation & Rsch., No. 202107Orig1s000, Korlym (mifepristone) Risk Assessment and Risk Mitigation Review(s) 9, 11 (Jan. 27, 2012), https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202107Orig1s000RiskR.pdf (hereinafter Korlym Review), attached hereto as Ex. M.

[64] *Id*. at 8.

sildenafil, do not have REMS restrictions."[65] Penicillin has a mortality rate three times greater than mifepristone.[66] Viagra has a mortality rate more than six times greater than mifepristone.[67] Tylenol overdose is one of the *most common* causes of liver transplantation in the U.S.—it leads to 56,000 emergency department visits, 2,600 hospitalizations, and 500 deaths per year in the United States.[68] No REMS applies to any of these drugs.

121. Not even opioids—some of the most dangerous drugs on the market—are subject to similar restrictions. REMS applicable to opiates require opioid manufacturers to offer optional training—a far cry from the mandatory, burdensome requirements imposed on mifepristone. Indeed, according to FDA, "[t]here is no mandatory federal requirement that prescribers or other [healthcare providers] take the training and no precondition to prescribing or dispensing opioid analgesics to patients."[69]

122. On June 21, 2022, ACOG and the American Medical Association (AMA) again urged FDA to eliminate the in-person dispensing and certification requirements, as "[b]arriers to accessing mifepristone do not make care safer, are not based on medical evidence, and create barriers to patient access to essential reproductive health care."[70]

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[65] Am. Acad. Fam. Physicians Congress of Delegates, Resolution No. 506 (Co-Sponsored C) – Removing Risk Evaluation and Mitigation Strategy (REMS) Categorization of Mifepristone 2 (May 24, 2018), https://www.reproductiveaccess.org/wp-content/uploads/2019/02/Resolution-No.-506-REMS.pdf.

[66] Greer Donley, *Medication Abortion Exceptionalism*, 107 Cornell L. Rev. 627, 651–52 (2022).

[67] *Id.*

[68] Agrawai & Khazaeni, *supra* n.20.

[69] U.S. Food & Drug Admin., Opioid Analgesic Risk Evaluation and Mitigation Strategy (REMS) (Apr. 3, 2023), https://www.fda.gov/drugs/information-drug-class/opioid-analgesic-risk-evaluation-and-mitigation-strategy-rems.

[70] Letter from Maureen G. Phipps, Am. Coll. Of Obstetricians & Gynecologists, and James L. Madara, CEO & Exec. Vice President, Am. Med. Ass'n, to Robert Califf, Comm'r, U.S. Food & Drug Admin. 2 (Jun. 21, 2022), attached hereto as Ex. N.

123. The same year, ACOG, AMA, and many other groups filed a citizen petition to FDA seeking to remove the REMS and add miscarriage management to mifepristone's indications.

124. The petition highlighted the same three troublesome remaining aspects of the REMS: the Patient Agreement Requirement, the Prescriber Certification Requirement, and the Pharmacy Certification Requirement.

125. As to the Patient Agreement Requirement, it should "be removed entirely because it is medically unnecessary and repetitive of informed consent, as a previous review conducted by [the FDA review team] determined in 2016."[71]

126. As to the Prescriber Certification Requirement, it "serves no benefit to patient safety" and is "redundant and unnecessary."[72] Additionally, the petition noted the privacy and safety concerns inherent in a certification system.[73] The petition also highlighted that because of the certification requirement, "clinicians who have already navigated mifepristone REMS compliance to provide abortion care . . . are almost always located in cities," making access particularly difficult for people living in rural areas.[74]

127. And, the petition urged FDA not to include a certification requirement for pharmacies because "research . . . suggests that the pharmacy requirement is unnecessary to ensure that mifepristone's benefits outweigh its risks and unduly burden[s] access."[75] Moreover, "[a]s

[71] Citizen Petition, Docket No. FDA-2022-P-2425, from Am. Coll. Of Obstetricians & Gynecologists et al. to Lauren Roth, Assoc. Comm'r for Pol'y, U.S. Food & Drug Admin., at 12 (Oct. 4, 2022) (hereinafter ACOG Citizen Petition), attached hereto as Ex. O.

[72] *Id.* at 13.

[73] *Id.* at 13–14.

[74] *Id.* at 14.

[75] *Id.* at 15.

with the certified provider requirement, the burdens associated with the certified pharmacy requirement will also fall disproportionately on poor and rural [patients], contrary to the REMS statute."[76]

128. FDA rejected the medical groups' citizen petition.[77] This is not surprising, as FDA has repeatedly brushed aside concerns raised by leading medical organizations and its own data that show that the REMS harms patients and providers and is medically baseless. The agency kept renewing the REMS—in 2016, 2019, 2021, and yet again in 2023. FDA retained these restrictions notwithstanding its periodic reviews of the post-marketing data, which have not identified any new safety concerns with the use of mifepristone for medical termination of pregnancy.

V. The REMS Has Always Been Contrary to the FDCA

129. FDA's imposition of the REMS, including the 2023 REMS, is contrary to its statutory authority under the FDCA. As described above, a "Risk Evaluation and Mitigation Strategy" (REMS) is an unusual overlay of requirements outside of the norm that FDA can choose to impose only when "necessary to ensure that the benefits of the drug outweigh the risks of the drug." 21 U.S.C. § 355-1(a)(1). And, FDA may impose an ETASU on a medication only if it is "associated with a serious adverse drug experience," which is defined as a medication that "results in" death or "immediate risk of death," "inpatient hospitalization or prolongation of existing hospitalization," "persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions," or "a congenital anomaly or birth defect," or that "may jeopardize

[76] *Id.* at 16.

[77] U.S. Food & Drug Admin., FDA-2022-P-2425-0003, Letter from Patrizia A. Cavazzoni, Dir., Ctr. for Drug Evaluation & Rsch., U.S. Food & Drug Admin., to Maureen G. Phipps, Am. Coll. Obstetricians & Gynecologists, denying Citizen Petition, Docket. No. FDA-2022-P-2425 (Jan. 3, 2023) (hereinafter ACOG Citizen Petition Denial), attached hereto as Ex. P.

the patient and may require a medical or surgical intervention to prevent [such] an outcome." 21 U.S.C. §§ 355-1(f)(1)(A), (b)(4).

130. Mifepristone has never come close to meeting these criteria. Indeed, FDA itself has repeatedly concluded that serious adverse events following mifepristone use are "exceedingly rare."[78]

131. The ETASU also violates the FDCA's requirement that such restrictions "not be unduly burdensome on patient access to the drug, considering in particular . . . patients in rural or medically underserved areas," and must "minimize the burden on the health care delivery system." 21 U.S.C. §§ 355-1(f)(2)(C)–(D).

VI. FDA's Decision to Retain the REMS Contributes to the Current Chaos and Ongoing Questioning of Mifepristone's Safety

132. Ensuring protected access to mifepristone—in line with all medical evidence—is more important now than ever, with abortion rapidly becoming criminalized across large swaths of the nation, and with anti-abortion zealots seeking to destroy the ability of any person *in any state* to use mifepristone.

133. The *only* actors who have *ever* attempted to suggest that mifepristone is unsafe are anti-abortion ideologues who ignore the conclusions of the AMA, ACOG, and every other mainstream medical and public health organization to have addressed the issue. Instead, they invoke junk science and purported experts whose opinions have been thoroughly discredited.[79]

134. Biased studies seeking to show that abortion by any method—whether medication or procedural—carries negative physical and mental health consequences have repeatedly been

[78] Ex. E (FDA 2016 Medical Review) at 47; *see also* Ex. I (Mifepristone U.S. Post-Marketing Adverse Events Summary).

[79] *See, e.g.*, Ex. D (Citizen Petition Denial) at 6.

deemed by the scientific community to be counter to the evidence. The National Academies concluded that "much of the published literature on" the topics of "abortion's long-term effects" on health and wellbeing "fails to meet scientific standards for rigorous, unbiased research."[80] When the National Academies considered only the "high-quality research" that met scientific standards, that research showed that "having an abortion does not increase a woman's risk of secondary infertility, pregnancy-related hypertensive disorders, abnormal placentation . . . preterm birth, breast cancer, or mental health disorders."[81]

135. Anti-abortion idealogues have now resorted to challenging the decades-old 2000 approval of mifepristone in the *Alliance* Case. *See All. for Hippocratic Med.*, 2023 WL 2913725, at *3.[82]

136. Two courts agreed with the plaintiffs in the *Alliance* Case and issued stays to some degree of FDA's actions on mifepristone, relying on the flawed science that the plaintiffs put forth. On April 7, 2023, a district court in Texas ordered an unprecedented stay of FDA's longstanding approval of mifepristone. *See All. for Hippocratic Med.*, 2023 WL 2825871, at *32. The court maintained that FDA's 2000 approval of mifepristone ignored "safety concerns," suggesting that the agency acquiesced to "political pressure to forego its proposed safety precautions." *Id.* at *27. Even though the challenged approval has been in effect for over twenty years, the court—citing

[80] National Academies Report, *supra* n.20, at 152.

[81] *Id.* at 153.

[82] *See also* Mot. for Leave to File Br. of Over 100 Reprod. Health, Rts. & Just. Orgs. as Amici Curiae in Support of Defs.-Appellants and the Mots. for Stay Pending Appeal at 6–9, *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 11, 2023); Unopposed Mot. for Leave to File Br. of Med. & Pub. Health Soc'ys as Amici Curiae in Support of Defs.-Appellants at 7, *All. for Hippocratic Med. v. FDA*, No. 23-10362 (5th Cir. Apr. 11, 2023) (identifying numerous courts that have rejected plaintiffs' experts and concluding that "[t]he so-called studies on which the District Court relied are not scientifically tested or sound; they are produced by anti-abortion advocacy groups or contain serious (and often well-documented) methodological flaws—or both.").

nothing more than plaintiffs' assertions in their brief—declared that medication abortion causes "physical and emotional trauma," "mental and monetary costs," and death. *Id*. at *29.

137. At the same time on April 7—almost to the minute—a district court in Washington issued an injunction in 17 states and the District of Columbia preventing FDA from deviating from the status quo—the 2023 REMS. The Washington court emphasized that it is "precisely FDA's role" to make safety and efficacy determinations, however, based on the same record Plaintiffs present here, FDA "did not assess whether mifepristone qualifies for REMS and ETASU." *Washington*, 2023 WL 2825861, at *8. Further, the district court found that FDA's repeated determination that "[s]erious adverse events . . . are rare" and that mifepristone "is safe and effective through 70 days gestation," along with its mystifyingly inconsistent approval of mifepristone for Cushing's syndrome without a REMS, suggest that FDA has ignored an important aspect of the issue before it when it issued REMS requirements repeatedly without scientific basis. *Id.*

138. Then, on April 12, the United States Court of Appeals for the Fifth Circuit compounded the confusion wrought by the Texas district court order, staying the decision only in limited part. *See All. for Hippocratic Med.*, 2023 WL 2913725, at *1. The panel stayed only the portion of the district court ruling that suspended FDA's 2000 approval of mifepristone, while declining to stay the district court's other holdings—essentially enjoining the 2016 and 2023 REMS. *Id.* at *21.

139. Providers in states covered by the Washington injunction may proceed with abortion care as usual under the Fifth Circuit order, but the Plaintiffs here, and their states, are left out, as are their patients.

140. The U.S. Supreme Court entered a stay of the Texas district court decision through the appeals process of the preliminary injunction order entered by the district court, and possibly longer if the Court decides to take the case up at the preliminary injunction stage. However, the Fifth Circuit will hear argument in the case as soon as May 17, and uncertainty continues to abound.[83]

141. For these reasons, states are continuing to stockpile mifepristone (and even misoprostol) because of the day-to-day, week-to-week uncertainty about whether and how providers can use mifepristone.[84]

142. Plaintiffs, however, do not have the resources to stockpile years of mifepristone, nor are they able to accommodate massive shifts to their practice every 24 hours. They require certainty about their provision of mifepristone to maintain their medical practices and provide high-quality, evidence-based care to their patients.

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[83] *See, e.g.*, Christine Fernando & Jeanine Santucci, *Dueling Federal Rulings Plunge Future of Abortion Pill into Legal Uncertainty*, USA Today (Apr. 8, 2023, 2:32 P.M.), https://www.usatoday.com/story/news/nation/2023/04/07/judge-revokes-fda-approval-key-abortion-drug-nationwide/11203402002 (describing providers' rush to shift to misoprostol-only protocols due to legal uncertainty); C.A. Bridges, *What is Mifepristone? Are Abortion Pills Legal in Florida?*, Gainesville Sun (Apr. 17, 2023, 2:22 P.M.), https://www.gainesville.com/story/news/healthcare/2023/04/14/abortion-pills-florida-mifepristone-misoprostol-what-they-are-how-get-them/7766021001 (describing confusion as "patients and providers try to understand the new and shifting laws, lawsuits and court rulings"); Jan Johnson & Michael Martin, *Supreme Court Ruling on Mifepristone Causes Uncertainty for Advocates*, NPR (Apr. 21, 2023, 11:30 A.M.), https://www.npr.org/2023/04/21/1171202676/abortion-pill-supreme-court (citing Michigan provider saying that "conflicting legal rulings and the wait for answers is complicating care and making it difficult to help patients").

[84] *See, e.g.*, Reis Thebault et al., *Democratic States Stockpile Abortion Pills as Access Rests in Courts*, Wash. Post (Apr. 21, 2023), https://www.washingtonpost.com/nation/2023/04/21/blue-state-abortion-pill-access (describing six states, representing a quarter of the U.S. population, that "have publicly pledged to stockpile abortion drugs"); Jen Christensen, *Concerned About the Courts, Some States and Universities are Stockpiling Abortion Drugs*, CNN (Apr. 12, 2023, 5:49 P.M.), https://www.cnn.com/2023/04/12/health/abortion-drugs-stockpile/index.html (University of Massachusetts and University of Washington stockpiling mifepristone; New York and California stockpiling misoprostol).

VII. Plaintiffs Do Not Need to File a Citizen Petition.

143. Plaintiffs are excused from any need to file a citizen petition under FDA regulations. *See* 21 C.F.R. §§ 10.30, 10.45. Such a filing would be futile because FDA has refused similar relief to that sought here when requested in 2020 by 21 states[85] and in 2022 by ACOG.[86] Moreover, when 17 states and the District of Columbia filed the Washington lawsuit in 2023, which seeks identical relief, the FDA opposed it, asserting in its brief that its decision to maintain the REMS restrictions on mifepristone was "reasonable." Defs.' Resp. Opp. Pl. States' Mot. Prelim. Inj. at 22, *Washington v. FDA*, No. 1:23-cv-3026-TOR (E.D. Wash. Mar. 17, 2023). There is no prospect that FDA would take a different view if Plaintiffs were required to submit a citizen petition now; there would only be harmful delay because the agency's own rule allows it 180 days to respond to citizen petitions, *see* 21 C.F.R. § 10.30(e)(2), and it often takes considerably longer to respond.

CLAIMS FOR RELIEF

COUNT I

(Administrative Procedure Act – Agency Action in Excess of Statutory Authority and Contrary to Law)

144. Plaintiffs reallege and incorporate by reference allegations in each of the preceding paragraphs of this complaint.

145. FDA's continued imposition of the REMS, and its promulgation of the mifepristone 2023 REMS, was a final agency action that is causing Plaintiffs irreparable harm for which they have no other adequate remedy under 5 U.S.C. § 704.

[85] Letter from Xavier Becerra, Cal. Att'y Gen, et al., to Alex M. Azar, Sec'y, U.S. Dep't of Health & Hum. Servs. & Stephen Hahn, Comm'r, U.S. Food & Drug Admin. (Mar. 30, 2020), attached hereto as Ex. Q.

[86] Ex. O (ACOG Citizen Petition); Ex. P (ACOG Citizen Petition Denial).

146. This Court must "hold unlawful and set aside agency action" that is, among other things, "not in accordance with law," "in excess of statutory jurisdiction, authority, or limitations, or short of statutory right" or "without observance of procedure required by law." 5 U.S.C. § 706(2).

147. Through the actions set out above, Defendants violated 5 U.S.C. § 706(2)(C) by acting in excess of statutory authority and contrary to law in continuing to impose the REMS and promulgating the mifepristone 2023 REMS contrary to its authorization in the FDCA.

COUNT II

(Administrative Procedure Act – Agency Action that is Arbitrary and Capricious)

148. Plaintiffs reallege and incorporate by reference allegations in each of the preceding paragraphs of this complaint.

149. FDA's continued imposition of the REMS, and its promulgation of the mifepristone 2023 REMS, was a final agency action that is causing Plaintiffs irreparable harm for which they have no other adequate remedy under 5 U.S.C. § 704.

150. This Court must "hold unlawful and set aside agency action" that is, among other things, "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law" 5 U.S.C. § 706(2)(A).

151. Through the actions set out above, Defendants violated 5 U.S.C. § 706(2)(A) by acting arbitrarily and capriciously in continuing to impose the REMS and promulgating the mifepristone 2023 REMS.

COUNT III

(Administrative Procedure Act—Action Contrary to Constitutional Right)

152. Plaintiffs reallege and incorporate by reference allegations in each of the preceding paragraphs of this complaint.

153. FDA's promulgation of the mifepristone 2023 REMS was a final agency action that is causing Plaintiffs irreparable harm for which they have no other adequate remedy under 5 U.S.C. § 704.

154. This Court must "hold unlawful and set aside agency action" that is, among other things, "contrary to constitutional right, power, privilege, or immunity." 5 U.S.C. § 706(2)(B).

155. FDA's promulgation of the mifepristone 2023 REMS treated similarly situated parties differently without adequate justification, and therefore violates the constitutional guarantee of equal protection in violation of 5 U.S.C. § 706(2)(B).

COUNT IV

(Equal Protection)

156. Plaintiffs reallege and incorporate by reference allegations in each of the preceding paragraphs of this complaint.

157. As described above, Defendants violate the equal protection guarantee of the Due Process Clause of the Fifth Amendment to the United States Constitution.

158. Through the 2023 REMS, FDA reduces access to a critical and time-sensitive healthcare service needed by pregnant people. And FDA treats providers, pharmacists, and patients who prescribe, dispense, or use mifepristone worse than providers, pharmacists, and patients who prescribe, dispense, or use nearly every other medication. FDA's actions are irrational and violate the Fifth Amendment under any standard of review.

PRAYER FOR RELIEF

159. WHEREFORE, Plaintiffs pray that the Court:

a. Declare, pursuant to 28 U.S.C. § 2201, that mifepristone is safe and effective and that Defendants' approval of mifepristone is lawful and valid;

b. Declare, pursuant to 28 U.S.C. § 2201, that the mifepristone REMS violates the Administrative Procedure Act;

c. Declare, pursuant to 28 U.S.C. § 2201, that the mifepristone REMS violates the United States Constitution;

d. Enjoin Defendants, pursuant to 28 U.S.C. § 2202, from enforcing or applying the mifepristone REMS;

e. Enjoin Defendants, pursuant to 28 U.S.C. § 2202, from taking any action under the REMS against any providers in Virginia, Montana, or Kansas.

f. Award such additional relief as the interests of justice may require.

DATED this 8th day of May, 2023.

Respectfully submitted,

/s/ Gail M. Deady
Gail M. Deady
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Rabia Muqaddam*
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Counsel for Plaintiffs

**Pro hac vice application forthcoming*

CERTIFICATE OF SERVICE

I hereby certify that on this 8th day of May, 2023, I filed the foregoing document with the Clerk of Court using the CM/ECF system, and I hereby certify that I will mail by United States Postal Service Certified Mail the document to the following non-CM/ECF participants:

United States Department of Health & Human Services
c/o General Counsel
200 Independence Avenue, S.W.
Washington, D.C. 20201

Xavier Becerra, Secretary
c/o General Counsel
Department of Health and Human Services
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United States Food and Drug Administration
Chief Counsel, Food and Drug Administration
ATTENTION: LITIGATION
White Oak Building 31, Room 4544
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Robert M. Califf, Commissioner
Chief Counsel, Food and Drug Administration
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Attorney General Merrick Garland
Attorney General of the United States
U.S. Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530-0001

I also hereby certify that on this 8th day of May, 2023, the foregoing document will be hand served to:

U.S. Attorney Christopher Kavanaugh
United States Attorney's Office

Western District of Virginia
U.S. Courthouse and Federal Building
255 West Main Street, Room 130
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/s/ Gail M. Deady
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Counsel for Plaintiffs

EXHIBIT 48

Declaration of Rebecca Tong

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, on behalf of itself, its staff, and its patients; et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; et al., Defendants.	Case No. 3:23-cv-00019-NKM

DECLARATION OF REBECCA TONG IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

1. I am a Co-Executive Director of Trust Women Foundation ("Trust Women"). Trust Women operates clinics offering reproductive health care, including abortion, contraceptive services, and gender-affirming care, with a focus on providing access for those in underserved communities. Trust Women opened its first clinic, South Wind Women's Center (doing business as "Trust Women Wichita"), in Wichita, Kansas on April 3, 2013. Trust Women opened a clinic in Oklahoma City, Oklahoma ("Trust Women Oklahoma City") in 2016.

2. As Co-Executive Director of Trust Women, I oversee operations at both Trust Women Wichita and Trust Women Oklahoma City. I am familiar with all aspects of our policies and practices and am frequently in contact with Trust Women's clinical staff and physicians. The facts I state here are based on my experience and information and knowledge I have obtained through my work for Trust Women.

3. I submit this declaration in support of Plaintiff's Motion for a Preliminary Injunction.

4. Trust Women Wichita provides reproductive health care, including both procedural and medication abortion, and contraceptive services.

5. Trust Women Wichita provides procedural abortions up to 21 weeks, 6 days of pregnancy, as measured from the first day of the patient's last menstrual period ("LMP").

6. Trust Women Wichita provides medication abortions up to 11 weeks LMP. The regimen used at Trust Women involves two medications, mifepristone and misoprostol. The patient takes the mifepristone at the clinic. The patient then takes the misoprostol approximately 24 to 36 hours later outside of the clinic.

7. Trust Women Wichita has provided medication abortion since it opened in 2013, and the clinic's safety record has been excellent. We have never faced a serious complication from medication abortion.

8. We used to provide these same services safely and effectively in our clinic in Oklahoma City, but we had to shutter abortion services when multiple abortion bans took effect in Oklahoma at or about the time *Roe* was overturned. We have pivoted our services to provide other care our Oklahoma City community needs, including gender-affirming care, and medication assisted treatment.

9. Until 2018, Trust Women Wichita offered a telemedicine clinic for medication abortion, but we were forced to stop that practice due to a Kansas state law. That law was very recently enjoined, and we are interested in restarting our telemedicine clinic if we are able to. We are particularly interested in pursuing the option to mail mifepristone, which would greatly expand our ability to help patients. We would start as soon as we can if mifepristone remains available and possible to dispense by direct to patient telehealth.

I. Providing Abortions Post-*Roe*

10. I have worked at Trust Women since the Wichita clinic opened in 2013, and it has always been challenging to provide care in a hostile environment like Kansas or Oklahoma, where we are targets for harassment and violence. But, the last year has been the hardest I have ever experienced. Since even before the Supreme Court's decision in *Dobbs*, our clinics have been in a constant state of whiplash from unending legal uncertainty around providing care. On the other side of this chaos are our very real patients who suffer every time we have to change course due to the latest legal or regulatory change or court decision. Now we have uncertainty even about whether and how we can use mifepristone to provide medication abortion. In the last year, we have had to modify every single system in our clinics. As healthcare providers, we need to plan ahead—we need certainty around whether and how we can see patients tomorrow or the next day without fearing that we will have to reorder our entire practice every 24 hours or turn patients away. We cannot look more than a few steps ahead because we cannot anticipate what the legal environment will look like next week.

II. The Mifepristone Risk, Evaluation, and Mitigation Strategy ("REMS")

11. Mifepristone has long been subject to medically unnecessary requirements known as the REMS. The FDA has followed at least some of the science and changed these requirements over the years; but the REMS remains and continues to interfere with access. The requirements that providers and pharmacies be certified and patients and providers sign agreements do nothing to improve patient care. Rather, they significantly add to the operational and logistical burden of providing medication abortion. We have to use a special pharmacy other than the one we use for all other medications.

12. The REMS also contributes to the stigmatization of medication abortion. When patients read the medication guide, they feel they are taking something that is riskier than it is. Further, the information collected through this unnecessary bureaucracy puts patient and clinician privacy in jeopardy, which is particularly concerning now that abortion is criminalized with very limited exceptions in 13 states. Further, we are limited to hiring physicians that are willing to become certified prescribers and potentially expose themselves as abortion providers.

13. We have decades of evidence demonstrating that medication abortion with mifepristone is safe, effective, and, for many patients, preferable. It is bizarre to us that mifepristone is subject to a REMS when its risk profile is on par with Tylenol.

14. These requirements are severe and, in light of the chaos we have experienced in the last year, detailed below, they have become extremely difficult and sometime insurmountable for some patients. We are challenging them now so that we can devote more of our time to patient care and not senseless requirements that burden our ability to provide medication abortion, can compromise patient privacy and confidentiality, and have no medical benefit. Until this court can rule on this issue, we ask that the FDA be enjoined from deviating from our current status quo of providing medication abortion.

a. S.B. 8 in Texas, its Oklahoma Copycats, and the Overturning of *Roe*

15. On September 1, 2021, before *Roe* was overturned, abortion was banned in Texas beyond approximately 6 weeks LMP due to the enactment of Texas S.B. 8. S.B. 8 was blocked and then un-blocked several times, sending massive shocks through the system of provision of care, as Trust Women Wichita and Trust Women Oklahoma City and our patients struggled to navigate the upheaval caused by abortion services being available and then unavailable repeatedly in Texas.

Patients were frantic trying to be seen. The emotional toll that time took on patients cannot be overstated.

16. Then in Oklahoma, the state legislature started enacting no less than 4 abortion bans in succession with different prohibitions and penalties. First, in May 2022, a 6-week S.B. 8-style ban took effect, then a total S.B. 8-style ban with inconsistent exceptions, and then a 1910 criminal ban revived by Oklahoma's trigger ban. Because the S.B. 8-style laws had immediate effect, we had to schedule patients in Trust Women Oklahoma City understanding that the next day we might not be able to see them. We watched the legislature and the Governor's actions every day to the minute, in order to understand and try to guess when and how exactly these laws would be passed and signed. We had no idea when those laws would take effect. Ultimately, they did, and we had to immediately cease our abortion services in Oklahoma City.

17. After *Roe* was overturned in June 2022, Texas, Oklahoma, Missouri, and Arkansas began enforcing their trigger laws, banning abortion entirely in those states with criminal penalties.

18. I cannot express how devastating it is for patients when we have to call to tell them we cannot see them for an appointment they desperately want and need because a new legal change or court case has tied our hands. We have had patients threaten to harm themselves because they do not wish to be forced to birth and are terrified that they will not be able to receive care.

19. This wave of criminalization and civil liability has forced desperate patients to travel hundreds of miles to seek care. Trust Women Wichita, as one of the few remaining clinics somewhat close to Texas, Oklahoma, and other ban states, has seen a massive increase in patients seeking care due to abortion bans. In 2021, Trust Women Wichita saw around 1500 patients. In 2022, we saw around 3500 patients. For the first 4 months of 2023, we have seen 2*000 patients*

already—on pace for 6,000 for the year. Around two-thirds of our patients are coming from out of state.

20. Most of our patients are already parents. Often, they drive all night with their families in order to see us. Many of the patients we are now seeing have extremely complex pregnancies, with varying health conditions and previous c-sections. We now have people coming directly to us from hospitals in ban states because they cannot get care even in medical emergencies. In no other area of medicine are people treated this way.

21. In response, we have expanded to providing abortion services four days per week with more physicians. But, that expansion does not come close to meeting the need for patients seeking abortion care at Trust Women Wichita. The current call volume for appointments is so high that it could support filling appointments seven days a week, 24/7. Since S.B. 8 took effect, it is not uncommon for us to receive tens of thousands of calls a day.

b. The Chaos Comes for Medication Abortion

22. Now, we face a new rollercoaster around the use of mifepristone. On April 7, a district court in Texas issued an order saying that mifepristone could no longer be used anywhere in the country and gave the FDA only a week to seek an emergency appeal.

23. We were shocked by this because regardless of what someone might think about the morality of abortion, decades of research shows that mifepristone is one of the safest drugs you can take with an extremely low rate of serious complications—it is as safe or safer than taking Tylenol, and it is less risky than many other drugs we use in our practice such as medications for sedation. We have never had a serious complication associated with medication abortion in our entire history. To the contrary, mifepristone is a medical advancement that improves the experience

of abortion for many patients—it is simpler, less expensive, more private, and imposes less discomfort.

24. We immediately worked to develop medication abortion protocols for a hypothetical situation in which we would not be able to use mifepristone. In anticipation of the decision and after, we spent hours training staff on an alternative protocol. When the Texas decision came down, we reached out to hundreds of patients to re-do the consent process that is required in Kansas 24 hours in advance. We had to review the new protocol with patients. Around two dozen patients called us that week because they were confused about whether they could receive their abortion.

25. But that same day, a district court in Washington issued an order requiring the FDA to maintain the status quo for mifepristone but only in select states. Kansas was not included in that order.

26. We also use mifepristone for preparation for procedural abortions because we find that it prepares the cervix faster than misoprostol, which others use. We did not know how these orders would affect mifepristone when used for that purpose.

27. Then, on April 12, the Fifth Circuit put part of the Texas order on hold. The Fifth Circuit's order said that while mifepristone could still be used, the FDA's changes to the REMS from 2016 onward were no longer in effect. We understood this to mean that mifepristone was available but had to be prescribed as if we were rewinding 7 years of medical progress. The pre-2016 REMS effectively prevent a physician from writing a prescription for mifepristone that would allow a patient to pick the drug up at pharmacy. We were considering how to expand our telemedicine program, including using direct to patient telehealth, when mifepristone's approval was suddenly up in the air. Mailing mifepristone would greatly expand the amount of care we are

able to provide. We also weren't sure if we could use the generic Genbiopro mifepristone we have used for years and acquired Danco's mifeprex even though they are identical products.

28. We bought around $20,000 of Danco's mifeprex that we did not even know we would ultimately be able to use, and we had to get registered with Danco. Trust Women is a small nonprofit, and we do not have the resources to stock years of mifepristone, but we bought what we could.

29. We were grappling with how to adjust when, hours before it was set to take effect, the U.S. Supreme Court put the Texas order on hold.

30. Throughout this time, we faced challenges in staffing the clinic. We work with 18 doctors, and 16 of them fly in to Kansas to provide care. We had doctors on standby, but as changes occurred, we didn't know exactly how to plan our physicians' shifts.

31. We are not a part of any of these cases and have been left to sort out how—in all of this uncertainty—to continue to provide quality, evidence-based patient care. And so, for the third time in one year, we are going through a period where we have had to make rapid, senseless changes to our practice that have dramatically harmed patients.

32. Although the Supreme Court ultimately stayed that district court decision pending the appeals process in the Fifth Circuit and possibly a petition for certiorari, we remain extremely uncertain about our provision of mifepristone going forward, especially given that the Fifth Circuit is hearing argument in the case on May 17. Will we be able to use the mifepristone we have beyond a few weeks from now? If we can, under what conditions can we go ahead? What other decisions from the Texas court, other courts, or the FDA are going to interrupt our provision of mifepristone next?

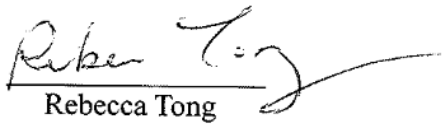
33. Abortion is an essential and time-sensitive service that pregnant people need to have available in order to live their lives with dignity and independence, and to preserve their health and lives. I clearly recall a mother who was desperate to bring her daughter in for care after S.B. 8. They traveled 13 hours to see us. She called us every day for a week, and every hour on the day of their appointment to make sure they could be seen after they made the journey. This confusion and terror is the result of all of this legal chaos. It is simply cruel to put pregnant people through this insanity, and it is all but impossible for us as providers to navigate.

34. Though abortion is extremely safe, the risks and complexity increase as pregnancy progresses. Delays also increase the stress and burdens of maintaining an unwanted pregnancy. This is particularly true for patients who have a medical condition that makes pregnancy a significant health risk or who are pregnant as a result of sexual assault or incest.

35. And, being unable to have a medication abortion specifically causes significant harm to patients. Some patients prefer medication abortion with mifepristone because it allows them to complete the abortion in private or allows them to feel more in control of the procedure. For others, medication abortion with mifepristone may provide them with the flexibility they need to fit the abortion into their schedules. Because experiencing a medication abortion is nearly identical to a miscarriage, patients can choose not to reveal their abortion to disapproving partners, family, or friends. This is a particular benefit for those who may be victims of domestic violence who are trying to conceal the abortion from their abusive partners. Likewise, medication abortion may be preferred by patients who are victims of sexual assault because it avoids any re-traumatization that could occur with a surgical abortion. Medication abortion may also be medically indicated for some patients for a variety of reasons. At Trust Women Wichita in 2021, almost half of our abortion patients chose a medication abortion with mifepristone.

36. If we are unable to get some certainty around our provision of medication abortion, we and our patients will continue to face disruptions and patients will thus be delayed in accessing care. We hope that the Court will preserve the status quo of our provision of mifepristone for the pendency of the litigation.

DATED: 5/5/2023



Rebecca Tong

EXHIBIT 49

Declaration of Nicole Smith PHD, MPH

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE; et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; et al., Defendants.	Case No. 3:23-cv-00019-NKM

DECLARATION OF NICOLE SMITH PHD, MPH, IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

NICOLE SMITH, PhD, MPH declares under penalty of perjury that the following is true and correct:

1. I am the Executive Director of Blue Mountain Clinic (the "Clinic"), a family practice and primary care services clinic in Missoula, Montana. Blue Mountain Clinic is one of the plaintiffs in this case.

2. For the past 46 years, Blue Mountain Clinic has provided patient-centered and evidence-based health care, education, and advocacy in Missoula County and beyond. Blue Mountain Women's Clinic first opened in 1977 as the first and only abortion clinic in the state of Montana. In 1991, the Clinic expanded its health services to include comprehensive family medical care to better serve its community.

3. I have been the Executive Director of Blue Mountain Clinic since August 2021. As Executive Director, I oversee all aspects of the Clinic's work, including the overall business operations of the Clinic, human resources and personnel management, fundraising, and budgeting,

as well as day-to-day clinic operations. I supervise our two medical directors who, in turn, oversee clinical operations. As a result, I am familiar with all aspects of the Clinic's work and patient care.

4. I am a fourth generation Montanan, and I have two decades of experience working on sexual and reproductive health in a variety of settings. Prior to joining Blue Mountain Clinic, I worked as a Research Scientist for the Center for Children, Families, and Workforce Development at the University of Montana College of Health. I have a PhD in Health Behavior from Indiana University's School of Public Health, a Master's degree in Public Health from Portland State University, and a Bachelor's degree in Psychology from Carroll College. I have published twenty peer-reviewed academic research articles, including one peer-reviewed commentary on the safety and efficacy of mifepristone.

Access to Abortion in Montana

5. Montana is a large and mostly rural state, with total size measuring over 147,000 square miles and is the fourth largest state in the country. With just over one million residents, Montana ranks 44th in population size. However, the state's population size grew by 11.5% between 2010 and 2021, highlighting the growing influx of new residents to the state. Montana is home to 13 federally recognized Tribes; seven sovereign Reservation communities are located in the state. Indigenous individuals comprise the state's largest minority racial group, representing 7% of Montana's population. Indian Health Services, a federal program, is subject to the restrictions of the Hyde Amendment and therefore abortion care is not available through IHS clinics located in Reservation communities. The state's largest population centers include Billings, Bozeman, Kalispell, Missoula, Helena, and Great Falls.

6. Abortion clinics are located in Billings, Missoula, Helena, Great Falls, and Whitefish, all except Billings are located on the western side of the state. The majority of residents

living in eastern Montana must travel several hundred miles and up to seven hours of driving time one-way, to reach a brick-and-mortar abortion provider. The eastern-western regions of Montana are separated by the Continental Divide of the Rocky Mountains. This means that for all seasons except a short three-to-four months of summer, drivers will frequently encounter hazardous road conditions that add logistical and travel barriers to accessing health care in western Montana's more urban city centers.

7. Montana is a critical site of access to abortion for people in the greater Northern Rockies and Plains regions. Abortion has never been as accessible in the region as it should be, but, since the U.S. Supreme Court overruled *Roe*, access has grown exponentially worse. Each of Montana's neighboring states—North Dakota, South Dakota, Wyoming, and Idaho—have passed draconian abortion bans, meaning that, today, Montana is bordered on all sides by states that have banned abortion, or where a court order has blocked an abortion ban. Despite escalating legislative attacks, discussed more below, Montana itself has retained a baseline for access to abortion, as a result of strong state constitutional protections for abortion.

Blue Mountain Clinic's Practice and Our Patients

8. Blue Mountain Clinic fully integrates family medicine, mental health counseling, reproductive and sexual health care, comprehensive gender-affirming care, and suboxone therapy into its medical practice. The Clinic has four full-time primary health care providers who are licensed to practice in Montana: two physicians and two physician assistants. We also have one licensed clinical social worker (LCSW) on staff who provides mental healthcare and counseling services.

9. The Clinic serves over 3,000 patients per year, accounting for over 7,000 visits. For many of them, Blue Mountain Clinic is their medical home—they turn to us whenever they need

health care.

10. About 25% of Blue Mountain Clinic's patients travel more than 50 miles (which takes approximately one hour or longer one-way, given weather and road conditions) to access services at the Clinic. Some travel even further, for example, from Deer Lodge—which is about 85 miles and over an hour and a half away. Others make use of the direct-to-patient telehealth program for abortion, and do not need to make this in-person trip.

11. Blue Mountain Clinic's family medicine practice offers care from pediatric care to elder care, and includes wellness exams, internal medicine, preventative care, and mental health. All four of the Clinic's primary health care providers serve patients as part of the Clinic's family medicine practice.

12. Blue Mountain Clinic's abortion care practice offers two options: medication abortion up to 11 weeks LMP and procedural abortion up to 21.6 weeks LMP. There are a few regimens for medication abortion, including mifepristone-misoprostol and misoprostol alone. For over two decades, Blue Mountain Clinic has used an evidence-based mifepristone-misoprostol regimen, and we have always had at least one provider who is a certified mifepristone prescriber.

13. In 2022, the Clinic launched its direct-to-patient telehealth program for medication abortion. This model enables patients to access abortion care without having to travel to the Clinic for an abortion. Patients consult with a provider remotely, and after counseling on the patient's options, including the risks and benefits of each, a review of patient medical history, confirmation of the patient's eligibility for medication abortion, and obtaining informed consent, the provider writes a prescription for medication abortion and abortion pills are mailed to the patient in Montana.

14. One of Blue Mountain Clinic's physicians provides both procedural and medication

abortion care, five days a week. Each physician assistant provides medication abortion in-person and via direct-to-patient telehealth, four days a week. Blue Mountain Clinic also has one locum (contract) physician who works in the Clinic on a contract basis, primarily to provide abortion care up to 21.6 weeks LMP or when no other clinician is available. Because the Clinic's physician assistants provide medication abortion, the Clinic prioritizes scheduling physicians to care for patients in need of procedural abortions.

15. In 2022, Blue Mountain Clinic provided about 400 abortions. Almost 40% of those abortions were for patients who are insured through Medicaid (which covers abortion care in Montana), and who are the most financially vulnerable in the state. Our patients seek abortion care for a variety of health, family, economic, and personal reasons. Many are parents who have decided that they cannot parent another child at that time, and some are young people who do not feel ready to carry a pregnancy to term because they want to pursue school or work opportunities. Others face serious health issues that make it dangerous to continue a pregnancy, some are in abusive relationships; and some patients we care for are pregnant as a result of rape or incest.

16. The availability of abortion care enables patients not to forego educational and economic opportunities due to unplanned childbirth, to provide care to existing family members, to avoid raising children with an absent, unwilling, or abusive partner, and to prevent health harms, pain, and suffering that can arise from carrying pregnancies to term and giving birth.

The 2023 REMS are Harmful and Unnecessary

17. Mifepristone is incredibly safe and effective, and our patients are highly satisfied with the medication abortion regimen they have been accessing for years. No other similarly safe drug is subject to a byzantine set of rules that do not advance patient care. Instead, the REMS simply contributes to the incorrect idea that mifepristone is unsafe and prevents it from being more

widely accessible.

18. Requiring our patients to sign the Patient Agreement and to have the Medication Guide adds unnecessary logistical mandates while providing care and it suggests to patient, and to the public, that mifepristone is unsafe when it is not. Despite the far greater risk that continuing a pregnancy and giving birth can entail, there is no requirement that our prenatal patients be given several pages of special instruction about the option of continuing a pregnancy—beyond what informed consent requires. For patients experiencing miscarriage, stating they are taking mifepristone "to end my pregnancy" can add confusion and pain to an already distressing experience.

19. Requiring prescribers of mifepristone and pharmacies that dispense mifepristone be specially certified means mifepristone is simply not as widely available as it should be. Blue Mountain Clinic is a family practice, that, unlike many other family practices, incorporates abortion care—and goes through the extra hurdles that sometimes requires. But, we—and our fellow family practice providers—should be able to simply write a prescription for mifepristone that our patients can pick up at their local pharmacy, as we do with all other medications with a similar safety and efficacy profile. Requiring both the clinician prescriber and the pharmacy to go through additional steps to be certified means, as a practical matter, mifepristone will be less available for our patients than medications that are just as critical to patient care and of comparable safety. We know from documented research that many family medicine, internal medicine, and OB/GYNs want to prescribe mifepristone for abortion care, but their hospital or clinic regulations prevent them from becoming certified prescribers because of the hyper-regulations of REMS

requirements for this medication.[1] Removing the REMS regulations would significantly expand the available pool of health care providers who could and who would prescribe mifepristone for abortion care and for miscarriage management.

20. The REMS requirements are severe and, in light of the chaos we have experienced in the last year, and how irrational these regulations are, the disruptions and the misinformation that has resulted, has become increasingly harmful. We are challenging them now so that we can devote more of our time to patient care and not to senseless paperwork that has the potential to compromise patient privacy and confidentiality and does not make administration of mifepristone any safer than it already is.

The REMS Contributes to the Chaos for Abortion Providers and Our Patients

21. Blue Mountain Clinic has provided abortion care for over 46 years. The chaos and uncertainty about the status of mifepristone—because it is used in abortion care, and, for that reason, it is subject to special, unnecessary rules— is part and parcel of the disruption that Blue Mountain Clinic has had to endure simply because it provides abortion care.

22. This year's state legislative session was one of the most heated on record. At one point, Blue Mountain Clinic was advocating against *13* egregious bills which seek to significantly restrict abortion access, and another five bills which discriminate against LGBTQ Montanans. The bills also perpetuate lies and inflammatory language meant to shame and stigmatize. None of them improve health outcomes or increase access to healthcare for families. Multiple proposed laws and policies included immediate or near-immediate effective dates, indicating that, should they become law, they could require Blue Mountain to immediately retool or fundamentally overhaul our

[1] Silpa Srinivasulu, et al., US clinicians' perspectives on how mifepristone regulations affect access to medication abortion and early pregnancy loss care in primary care, 104 Contraception 92 (July 2021), https://www.sciencedirect.com/science/article/pii/S0010782421001335.

practice.

23. Blue Mountain Clinic is now also contending with the threats to mifepristone. The clinic developed medication abortion protocols to implement should mifepristone be considered unusable as a result of any court order in the Texas *Alliance* case. Because we had only been certified prescribers with GenBioPro, the manufacturer of generic mifepristone, we ensured our clinicians were also certified prescribers with Danco, the manufacturer of Mifeprex, the brand name mifepristone, should that become the only version we could use—even though they are the same product.

24. And we have tracked the fast-paced, dizzying legal process, the outcome of which could, at a moment's notice, impact whether and how Blue Mountain prescribes mifepristone. First, on April 7, the Texas court issued a ruling claiming to take mifepristone off the market, while putting the order on hold for 7 days. Five days later, on April 12, the Fifth Circuit indicated it was further modifying mifepristone's status—although the drug would still be on the market, we were going back to a time when a pre-2016 version of the REMS governed, and the generic had not yet been approved. Two days later, the U.S. Supreme Court kept this on hold until April 19 and then extended that until April 21. On April 21, the U.S. Supreme Court issued a stay of the Texas court's preliminary injunction, pending appeal of that injunction at the Fifth Circuit and pending any request that the Supreme Court review what the Fifth Circuit decides.

25. I also understand that another lawsuit was filed in Washington State by 17 states and the District of Columbia, where a court enjoined the FDA enforcing the *Alliance* order in those states. Montana did not join with the other plaintiffs in that case, and Blue Mountain is not protected by that order. Instead, Montana's attorney general has asked to intervene in that case to restrict access to mifepristone, despite pre-viability abortion being legal in Montana.

26. During this period of instability, Blue Mountain marked on March 29 the 30-year anniversary of the devastating arson which destroyed the clinic in 1993. As we reflect on that somber anniversary, we are once again working to provide high-quality care in an environment meant to stoke anger and violence. And the disruptions in the delivery of health services—whether caused by direct harassment and violence, or obstruction and intimidation in the form of constantly changing laws and policies that impact the care we provide—harm our patients in similar ways. As Willa Craig, the Executive Director of the Clinic at the time of the 1993 firebombing, said then, it is not only our patients seeking abortion care who are impacted by anti-abortion harassment, but also "our prenatal patients, the families that we have served over the years in every way, by delivering their babies and immunizing their children, to the patients of our internist who provides care for our many elderly patients, and our therapist who spends much of her time in adoption counseling."

27. Our busy family practice works to be nimble and accommodating—to best serve our patients and our staff. One of our physicians, whose family medicine practice includes abortion care, is currently booked months out for family medicine appointments. Abortion is time-sensitive health care, and Blue Mountain Clinic works to schedule appointments for patients seeking abortion care as soon as we are able to. We are the only clinic in Montana that provides abortion care five days per week. The threat of ever-changing law and policy disrupts and strains our clinicians, administrative staff, and confuses our diverse patient population, to the point where patients may believe medication abortion is no longer a legal option for them. Each of us needs to be able to plan, to know what our schedule will look like the next day or the next week (to the best we are able), and so any energy spent on emergencies is about emergent issues our patients bring to us— emergencies should not be foisted upon us by courts or legislators.

Disrupting Access to Mifepristone By Mail

28. Although Blue Mountain Clinic's direct-to-patient telehealth abortion program for medication abortion is relatively new, it is critical for our patients who face the most challenges accessing in-person care, including those who would be traveling from more rural areas, Indigenous individuals who must travel from Reservation communities where there is no abortion access, people with disabilities, and people who struggle with gas money or those who do not have adequate transportation (like vehicles that can handle Montana's harsh winter weather). People who need to keep their abortion confidential because they live with an abusive partner, people who do not have control over their work schedule, or those who have to arrange for childcare, also benefit from the comparative ease of our direct-to-patient telehealth program.

29. For some, the requirement of an in-person visit is insurmountable and would cause patients to forgo abortion care. Others would try to manage the logistical arrangements—from time off of work or school, to childcare, and adequate transportation—but gathering the money for all of that can take time, pushing people further into pregnancy, and increasing the actual costs of obtaining an abortion later in pregnancy. Delay means a person continues to endure the symptoms and risks of pregnancy, and it can mean they are pushed too far to be eligible for a medication abortion or pushed beyond the point at which abortion is available in Montana.

30. As already noted, Montana is a huge and mostly rural state. Accessing medication abortion via direct-to-patient telehealth can be the difference between accessing abortion care or not. Reinstating a ban on dispensing mifepristone by mail would take mifepristone off the table as an option for these patients, who otherwise may be unable to make the in-person visit for a procedural abortion. As the FDA already acknowledges, there is simply no valid reason to turn the clock back and reimpose this barrier to a safe, effective medication that has been on the market for

23 years.

Restricting Certified Prescribers to Physicians

31. Blue Mountain Clinic has long relied on advanced practice clinicians to provide care, including abortion care. We currently have two physician assistants, both of whom provide medication abortions, and one of whom has done so for over 15 years. They are both exceptional, compassionate providers who our patients rely on for sensitive, essential care. State law has required that physician assistants practice under the supervision of a physician (for any care they provide, not only abortion care). Just last month, however, Montana passed a law (which also took effect immediately) that removed the physician supervision requirement, paving the way for further expansions in access to care for Montanans.

32. At the very same time, the REMS threatens to move mifepristone provision backward. Reinstating a requirement that permits advance practice clinicians, including PAs, to provide mifepristone, but requiring that a physician be the certified mifepristone prescriber—to order and prescribe the medication—makes no sense, undermines the licenses and contributions of advance practice clinicians, and overall, will limit access to this safe, essential medication.

33. Additionally, I understand that rolling back to the pre-2016 REMS threatens patients' access to mifepristone from All Families Healthcare, where the only clinician is a nurse practitioner. Blue Mountain Clinic is the next closest provider—though still approximately a three-hour drive one-way. When there was no abortion provider in the Kalispell area from around 2014 to 2018, before All Families Healthcare opened in 2018, Blue Mountain Clinic's clinicians were far busier with abortion patients. Reinstating the physician-only restriction for certified mifepristone providers would propel us backward and would increase travel barriers for Montanans for no valid reason whatsoever.

34. Decades of evidence and experience demonstrate that medication abortion with mifepristone is safe, effective, and the preferred option for many patients. As people in the health care field, we are trained to follow evidence and experience. There is no reason to continue maintaining the REMS at all. At a minimum, however, maintaining the 2023 REMS as the legal processes proceed would provide Blue Mountain Clinic, our providers, and patients, some certainty and stability.

DATED: 5 May 2023

Nicole Smith

EXHIBIT 50

Declaration of Helen Weems MSN, APRN-FNP

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	Case No. 3:23-cv-00019-NKM

DECLARATION OF HELEN WEEMS MSN, APRN-FNP, IN SUPPORT OF PLAINTIFFS' MOTION FOR A PRELIMINARY INJUNCTION

HELEN WEEMS, MSN, APRN-FNP declares under penalty of perjury that the following is true and correct:

1. I am a nurse practitioner licensed to practice in Montana, and one of the plaintiffs in this case. I am the founder, owner, and sole clinician at All Families Healthcare ("All Families"), a sexual and reproductive health clinic in Whitefish, Montana, which opened in 2018.

2. I am also the only clinician providing abortion care in Northwest Montana. The next closest abortion provider is almost a 3-hour drive away, each way. Before All Families opened in 2018, the Northwest region had been without an abortion provider since 2014. And, prior to 2014, another advanced practice clinician—Susan Cahill, a physician assistant—was the only abortion provider in the region for many years.

3. I have a master's degree of science in nursing, family practice, from Vanderbilt University in Nashville, Tennessee. I am an advanced practice registered nurse, and I have been

board certified in family practice since 1999. I have full and independent practice authority in Montana—I do not practice in any official collaborative or supervisory relationship with a physician. I also have independent prescriptive authority from the Montana Board of Nursing. Additionally, I have a U.S. Drug Enforcement Authority ("DEA") license, which permits me to prescribe schedule II through V controlled substances.

4. For 22 years, I have provided health care services as a certified nurse practitioner. I have always provided patient-centered care based on trust and respect for my patients' decisions and use that same approach at All Families.

5. All Families serves nearly 600 patients per year, accounting for approximately 2,000 patient visits. We provide comprehensive sexual and reproductive health care services, including LGBTQ+ care and gender-affirming care; gynecological exams; same-day access to the full spectrum of contraceptive options, including insertion of IUDs and implants; diagnosis and treatment of sexually transmitted infections; miscarriage management; and abortion services.

6. At All Families, I provide medication abortion up to 11 weeks LMP and aspiration abortions up to 12 weeks and 6 days LMP. In 2022, I provided approximately 260 abortions. Medication abortion makes up well over half of the abortion care I provide—so far in 2023, medication abortion has been between 65% and 90% of the total abortion care I provide each month.

7. There are multiple regimens for medication abortion, including with mifepristone and misoprostol and with misoprostol alone. Since I became a certified mifepristone provider in 2018, I have used a mifepristone-misoprostol regimen for medication abortion. Patients obtain the medications from me at the clinic, or via mail after a telehealth visit (also called "direct-to-patient" telehealth). During a telehealth visit, I consult with a patient remotely about their available options,

review their prior medical history, and confirm the patient is eligible for medication abortion. I then write a prescription for mifepristone and misoprostol, which are dispensed via mail to the patient in Montana.

8. The mifepristone-misoprostol regimen for medication abortion is safe, effective, and evidence-based, and mifepristone is one of the safest medications available. While misoprostol-only is also a safe, effective, and evidence-based regimen used worldwide for medication abortion, mifepristone is a medical advancement that is preferable for many patients. The mifepristone-misoprostol regimen tends to have fewer uncomfortable side effects for patients. Evidence suggests that mifepristone is more effective than misoprostol alone, meaning there is a lower likelihood of ongoing pregnancy which would require follow up care—either additional medication or a procedure. Where both regimens are available, I prefer to use the mifepristone-misoprostol regimen. And my patients deserve the benefit of that medical progress.

9. My patients seek abortion services for a variety of reasons: some lack the financial means to raise a child; others are not ready to become a parent; many have physical and emotional health issues that would be exacerbated by continuing a pregnancy. In every circumstance, my patients deserve to be able to make the best decision for themselves, in consultation with the people they trust.

The 2023 REMS Has Imposed Unnecessary Restrictions on Patients and Providers

10. As a small, sole clinician practice in Whitefish, Montana, I am used to being nimble and innovative, to best serve my patients. As an abortion provider, however, each year, I am forced to confront increasing instability from hostile policies meant to undermine—not improve—the care I provide my patients.

11. The uncertain status of mifepristone is yet another one of those measures. The mere fact that it is subject to a REMS without any valid reason contributes to the idea that mifepristone

is unsafe and provides anti-abortion activists with unfortunate opportunities to further interfere with its accessibility.

12. The additional paperwork—the Patient Agreement and Medication Guide—suggests to patients that there is something to be concerned about with mifepristone, above and beyond other drugs that are equally safe.

13. For example, just before the Patient Agreement was updated in 2023, it included a statement that patients agreed to bring the Medication Guide to an emergency room in the rare event that they sought such care. But there is no reason for patients to take the Guide with them. And doing so can expose them to anti-abortion harassment and hostility in a health care setting where they deserve and should be able to expect compassion and care. Patients who take mifepristone for miscarriage are at the same risk because the Guide speaks about taking mifepristone for abortion.

14. The current Patient Agreement and Medication Guide can continue to be confusing for patients. For instance, both instruct that a patient take misoprostol 24 to 48 hours buccally after mifepristone. That does not account for the evidence-based protocol for vaginal administration of misoprostol, in which a patient takes misoprostol 6 to 72 hours following mifepristone. This protocol can be preferable for some patients who need or want more control over the timing of the medication abortion process—for example, for emotional reasons, or childcare or work constraints.

15. The special certification requirements for prescribers and pharmacists gate-keep access to mifepristone for no valid reason. Pharmacy certification means mifepristone is only available at select pharmacies that go through the hoops to become certified. It puts up an unnecessary roadblock for pharmacies that effectively prevents me from writing a prescription for

mifepristone a patient could pick up at local pharmacy as they do for many medications. And the prescriber certification and agreement requirements are unnecessary roadblocks for health professionals who can otherwise prescribe medications under their state licenses.

The Increasingly Hostile Legal and Policy Environment in Montana

16. When my clinic opened, I had to sue the State to block a criminal law that prevented me from providing abortion care because I am a nurse practitioner, rather than a physician. No similar law prevents me from providing the identical care to patients who need it to manage a miscarriage. The law I challenged prevented me from providing abortion care simply because it is abortion care. That law has been blocked since shortly after All Families opened in 2018. But, with each step in the judicial process, I wait for a court to decide whether I will be able to continue to provide abortion care I have been providing safely in Montana for 5 years.

17. In 2021, during the COVID-19 pandemic—which itself caused health care practices to quickly adjust to new circumstances—I and other Montana abortion providers waited on whether a court would block a set of abortion restrictions. One of those laws would have ended All Families' medication abortion by mail program, which had then become (and remains) critical to reach patients whose schedules make it challenging to make an in-person clinic visit or who live hours away, in remote rural areas of this vast state, or who opt to have an abortion in the privacy of their home.

18. Again this year, the State passed numerous restrictions on abortion, some with immediate or near-immediate effective dates. Individually and together, these policies could—on a moment's notice—decimate access to abortion care in Montana, which, today is bordered on all sides by states that have banned abortion, or where a court order has put a ban on hold. The instability into which mifepristone has been thrown—and therefore thrown my clinic and my patients—is no different.

The Chaos Created by the Texas *Alliance* Case

19. In advance of the Texas district court's ruling in the *Alliance* case, I developed medication abortion protocols without mifepristone. On Friday, April 7, the Texas ruling came down, apparently ordering mifepristone off the market. But the order would not take effect for 7 days. Then on Wednesday, April 12, the Fifth Circuit ruled, apparently ordering that, although mifepristone might still be on the market, we were going backward almost a decade, to the pre-2016 rules under which the generic form of the drug was no longer approved; I, as a nurse practitioner, could not be a certified mifepristone prescriber as I have been for 5 years; and All Families apparently would not be able to maintain its mifepristone by mail program with mifepristone. Additionally, for several years I had been a certified prescriber with GenBioPro (the generic manufacturer). After the Fifth Circuit ruled, I communicated with Danco (the manufacturer of the brand name drug) to ensure I remained a certified prescriber with Danco in case even though they are the same product, the generic became unavailable as the Fifth Circuit ruled—and assuming there was a way I could remain a certified prescriber as a nurse practitioner at all.

20. While still trying to sort through which set of rules abortion care might be governed by on Monday, the U.S. Supreme Court granted on Friday, April 14, another short pause—until 11:59 pm Eastern Time on Wednesday, April 19. That stay was then extended another two days, until Friday, April 21, at 11:59 pm Eastern. As I waited for notice from yet another court, I had to consider: When I saw patients on Tuesday, April 25, what set of restrictions would mifepristone be subject to? Would I be able to prescribe it? How much notice will my patients and I have? And what will the next weeks and months bring in this legal back and forth?

21. On Friday, April 21, the U.S. Supreme Court issued a stay that kept the status quo—the lower court orders would not take effect pending the Fifth Circuit's consideration of the appeal, and through the U.S. Supreme Court's review of that appeal, if that review occurs. For the next

few weeks, then, mifepristone would remain available, subject to 2023 restrictions. The legal back and forth, however, is not over. I still need to pay close attention to rapid legal developments in cases I am not involved in—unlike most other health care providers.

22. This is not how any other type of health care is practiced. It is not how any other small business is expected to operate. And it is not how any other patients are treated. Patients need to know whether they will be able to have their appointment the next day. I need to know whether I will see a patient the day they are scheduled. Especially as a small, solo practice, I need to know that when I buy medication, I will be able to use it. The instability and disruption my patients and I face simply because I provide and they seek abortion care is unrelenting, unjust, and unnecessary. It is also a deliberate effort to eliminate access to safe, compassionate abortion care.

23. I understand that a competing lawsuit brought in federal district court in Washington by 17 states and the District of Columbia has resulted in an order enjoining the FDA from enforcing the *Alliance* order in those states. Montana did not join that case initially, and I am not protected by that order. In fact, Montana's attorney general had asked to join the case as an intervenor to restrict the availability of mifepristone.

24. The threat of court orders turning back time to try to reinstate restrictions on mifepristone that were in place years ago remains. For example, the changes to the FDA's regulations that the Fifth Circuit ordered on April would be devastating to my practice.

Restricting Certified Mifepristone Prescribers to Physicians Only

25. Reinstating the physician-only certified prescriber requirement would mean I could no longer prescribe mifepristone as I have done for the last 5 years. As the only clinician at All Families, I am also the only certified mifepristone prescriber. Although the pre-2016 REMS permitted advance practice clinicians to provide mifepristone under the supervision of a physician

who is a certified prescriber, I do not work with a physician, and do not need a physician to prescribe mifepristone. As the only clinician at All Families and the only abortion provider in Northwest Montana, reverting to the old physician-only certified prescriber requirement could leave patients with no mifepristone provider.

26. Advanced practice clinicians have been critical to maintaining or restoring access to abortion in this region—including access to mifepristone—and this requirement would once again cut off that access.

27. Additionally, the requirement denies patients access to their *chosen* provider if that provider is me simply because I am a nurse practitioner. I have developed trusting relationships with my patients who come to me seeking intimate care. For 5 years I have provided that care with respect and compassion, free of judgment. This has made All Families a staple in Whitefish, beloved by the community. But preventing patients from accessing a safe, effective medication from me—for no other reason than an arbitrary distinction based on my credentials, not my experience or expertise—and in conflict with state licensure, makes no sense. It is unnecessary, disruptive for the patient, and strips them of a right to see a provider they trust.

28. Further, All Families' access to mifepristone will impact people from across Montana who seek medication abortion from me. Under the reinstated requirement, those patients, too, could seek this elsewhere—at one of the few clinics with physicians who provide abortion services in this state.

29. As the FDA itself concluded, restricting certified mifepristone prescribers to physicians only goes against overwhelming evidence and experience, including in Montana, which

demonstrate that advanced practice clinicians independently provide safe and effective abortion care on par with our physician counterparts. A consensus in the medical community agrees.[1]

30. Just as there is no reason to single out abortion care from the other care I provide, there is no reason to single out the mifepristone-misoprostol regimen simply because I am the clinician prescribing it. I can continue to prescribe potentially dangerous and addictive drugs, including, for example, Tylenol with codeine. Mifepristone is demonstrably safer than these medications, and, as the FDA itself knows, there is simply no valid reason to go backward and limit access to it.

Banning Mifepristone By Mail

31. More than half of all the abortion care I provide is medication abortion and more than half of the medication abortion care I provide is medication abortion by mail. That expansion in care opened up when a court order blocked the FDA from enforcing the in-person dispensing requirement in 2020. The FDA then temporarily suspended the requirement in 2021 and solidified that by updating the REMS in 2023 to eliminate this requirement.

32. The availability of mifepristone by mail has been critical to my patients. It provides flexibility and discretion, particularly for those who cannot take time from work, find childcare, or whose privacy would be jeopardized by making an in-person visit. It is also ideal for my many patients who live in the remote, rural regions of the state, which can be hours from All Families or the nearest clinic. Some live in the northeastern part of the state, about 9-10 hours away, and would otherwise have to travel through treacherous mountain passes and inclement weather to access

[1] *E.g.*, Nat'l Academies of Sciences, Engineering, and Medicine, Committee on Reproductive Health Services, *The Safety and Quality of Abortion Care in the United States* (2018); Tracy A. Weitz, et. al., *Safety of Abortion Performed by Nurse Practitioners, Certified Nurse Midwives, and Physician Assistants Under a California Legal Waiver*, 103 Am J. Pub. Health 454-461 (2013).

abortion care. Patients may not have gas money or cars that can reliably and safely make it on these roads.

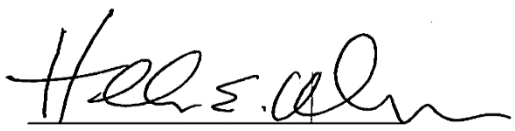
33. As the FDA's own decision to remove the ban on dispensing mifepristone via mail, reinstating the ban on mailing would propel patient care backward, with absolutely no benefit.

34. Before launching the medication abortion by mail program, patients would cancel or not show up to in-person appointments. During follow up calls, patients would say that something came up that made making the appointment impossible: they could not take off from work, a family member did not show up to take care of the kids, their car had broken down or could not handle the weather, they could not afford gas to travel to the clinic, or they could not discretely attend the appointment for fear of someone finding out. Since starting our telehealth and mail program, cancellations or no-shows are far more rare, and patients are able to access private, time-sensitive, safe and effective abortion care.

35. There is no basis to continue any of these restrictions in light of the established safety of mifepristone.

36. Providing high-quality abortion care in an increasingly hostile environment is challenging enough without having to contend with the fallout from the Texas *Alliance* case. At a minimum, having certainty that the status quo of regulation to which mifepristone was subject on April 7, 2023, applies, would allow All Families to continue to provide basic, safe, and effective care for our patients.

DATED: May 5, 2023



Helen Weems, APRN-FNP

EXHIBIT 51

Declaration of Amy Hagstrom Miller

IN THE UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF VIRGINIA

WHOLE WOMAN'S HEALTH ALLIANCE, on behalf of itself, its staff, and its patients; et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION; et al., Defendants.	Case No. 3:23-cv-00019-NKM

DECLARATION OF AMY HAGSTROM MILLER IN SUPPORT OF PLAINTIFFS' MOTION FOR PRELIMINARY INJUNCTION

AMY HAGSTROM MILLER hereby declares under penalty of perjury that the following statements are true and correct.

1. I provide the following testimony based on my personal knowledge and review of Whole Woman's Health Alliance's, Whole Woman's Health's, and Whole Woman's Health of the Twin Cities, LLC's business records in support of Plaintiffs' Motion:

2. The clinics I operate are independent abortion providers, or abortion clinics that are not affiliated with any national organization (such as Planned Parenthood). Independent abortion providers provide approximately 60% of abortion care in the country.

3. I have been working in the abortion care field since 1989. I have done virtually every clinic job over the past three decades, from receptionist to sonographer to pathology technician to surgical assistant to counselor. I have spent thousands of hours talking with abortion patients over the course of my career. In my current role, I oversee all operations at the WWH and WHHA clinics as well as WWH's Virtual Program, from staff management, to clinic

security, to clinical services for patients. I am thoroughly familiar with all aspects of abortion clinic operations and patient care.

4. WWH was founded in 2003 and we have been providing medication abortion from the beginning. I, along with our clinicians, management, and staff, have lived through each iteration of the FDA's changes to the approval, labeling, and safety requirements of mifepristone. We have operated within the constraints of the Risk Evaluation and Mitigation Strategy ("REMS") which, far from improving our patients' experience with mifepristone, has made it more burdensome and difficult for patients to access. While each iteration of the REMS has posed challenges to our staff and our patients, the last several weeks have been the most challenging.

Whole Woman's Health of Charlottesville

5. I am the President and Chief Executive Officer ("CEO") of Whole Woman's Health Alliance ("WWHA").

6. WWHA is a nonprofit organization incorporated under Delaware law. Its mission is to provide abortion care in underserved communities, shift the stigma around abortion in our culture, and ensure that every pregnant person deserves the compassion, respect, and dignity of being able to safely and legally end a pregnancy.

7. WWHA currently operates abortion clinics in Charlottesville, Virginia, Bloomington, Minnesota, and South Bend, Indiana.

8. As President and CEO of WWHA, I oversee all aspects of the organization's work.

9. Whole Woman's Health of Charlottesville ("WWH of Charlottesville") provides abortion services up to 16 weeks, as dated from the first day of the patient's last menstrual period

("LMP"), including medication abortion up to 11 weeks LMP. We provide medication abortion up to 11 weeks consistent with evidence-based practice around the country.

10. Since WWH of Charlottesville started providing medication abortion in October 2017, it has been providing it using the FDA approved mifepristone/misoprostol regimen.

11. WWH of Charlottesville does not currently have any advanced practice clinicians providing abortion care but is actively recruiting for such providers.

12. The patients we treat at WWH of Charlottesville largely travel to our clinic from small towns or rural areas of Virginia without abortion providers or from out of state. Most patients travel from at least 1.5-2 hours away, and most require financial assistance to cover the cost of their abortion. WWH of Charlottesville serves large swaths of Appalachia, including patients from West Virginia, Kentucky, and Tennessee (where abortion is now banned) and Georgia (where a 6-week ban is in effect). WWH of Charlottesville provides abortion care to approximately 750 patients per year, and approximately 60% of those receive medication abortion.

Whole Woman's Health of Alexandria

13. I am also the President and CEO of Whole Woman's Health, LLC ("WWH").

14. WWH currently operates an abortion clinic in Alexandria, Virginia, d/b/a Whole Woman's Health of Alexandria ("WWH of Alexandria). WWH also operates abortion clinics in Baltimore, Maryland and Albuquerque, New Mexico.

15. As President and CEO of WWH, I am responsible for the management of these clinics and therefore am familiar with our finances and operations, including the services we provide and the communities we serve.

16. WWH of Alexandria provides abortion services up to 16 weeks LMP, including medication abortion up to 11 weeks LMP.

17. WWH of Alexandria originally opened in 2019 under the name Whole Woman's Health and Family Center and began using the d/b/a name Whole Woman's Health of Alexandria in 2022. Since opening, it has provided medication abortion using the FDA approved mifepristone/misoprostol regimen.

18. WWH of Alexandria currently employs a nurse practitioner who provides medication abortion to patients in-clinic, and has employed other advanced practice clinicians in the past. Since the clinic opened, nurse practitioners have provided around 1,500 medication abortions, which is more than 40% of the total medication abortions.

19. WWH of Alexandria serves a remarkably diverse population of patients, most of whom require financial assistance, and 6-7 languages are spoken by both our patients and our staff. Because WWH of Alexandria is close to a large airport, many of our patients travel to us by plane from states where abortion in banned. Patients travel from West Virginia, Kentucky, Tennessee, and Georgia, and other states in the deep south, including many patients from Texas. WWH of Alexandria provides abortion care to approximately 2,300 patients per year, and approximately 64% of those receive medication abortion.

Whole Woman's Health's Virtual Abortion Care

20. I am also the President and CEO of Whole Woman's Health of the Twin Cities, LLC, which has operated a virtual healthcare program since August of 2021 that provides telehealth services for medication abortion in Virginia, Maryland, Minnesota, New Mexico, and Illinois ("WWH's Virtual Program").

21. WWH's Virtual Program provides telehealth medication abortion services up to 11 weeks LMP using the FDA approved mifepristone/misoprostol regimen.

22. WWH's Virtual Program provides medication abortion to approximately 2,400 patients per year, and the majority of those patients seek telehealth in Virginia. Around half of our virtual patients live in the states where we provide telehealth, while the other half travel to those states from other places. For our Virginia patients specifically, around half are Virginians who choose telehealth over coming to a clinic in person. Many patients require funding to pay for their telehealth abortion, both for the visit and any associated travel to the states where telehealth is available.

The REMS Has Led to Chaos in the Healthcare System

23. As abortion providers who, until *Roe v. Wade* was overturned in June 2022 operated abortion clinics in Texas, we are no stranger to the instability created by anti-abortion laws and policies. The chaos regarding the legal status of mifepristone over the last several weeks is reminiscent of our prior experiences in Texas and elsewhere.

24. Before being forced to close our Texas clinics in 2022, WWH and WWHA operated multiple abortion clinics in Texas. For years, regulatory interference in Texas caused us to endure constant service disruptions, ranging from changing our medical practices and protocols, to mandatory construction remodeling, to temporary or permanent closures due to rapid fire judicial orders. The result was incredibly destabilizing for our staff and patients. As those outside the field fail to grasp, healthcare practices cannot change overnight.

25. For example, in 2013, Texas passed House Bill 2, a law that required all abortion facilities to be licensed ambulatory surgical facilities and all abortion providers to have local hospital admitting privileges. Because WWH lacked sufficient physicians with admitting

privileges in Beaumont and Austin, we had to shut those clinics down. Additionally, our clinic in McAllen was shut down for eleven months and was only reopened because of an injunction awarded by a district court. Ironically, one of our physicians in Austin was able to obtain admitting privileges in Fort Worth, and so he commuted by plane in order to keep our clinic in Fort Worth open. While H.B. 2 was ultimately struck down in 2016 as unconstitutional by the Supreme Court, WWH was severely strained by the litigation.

26. In early 2020, we had a similar experience when the Texas Governor issued a COVID-19 executive order that forced all of the abortion providers in the state to stop providing abortions for around three weeks. While there were brief periods of time during those three weeks when court orders technically permitted us to reopen, practically speaking, it was impossible to call patients back quickly enough before another court order shut down abortion access once again.

27. In 2021, we again faced on-again off-again chaos when S.B. 8, the 6-week abortion ban enforced via a vigilante bounty-hunting scheme, took effect. A district court entered a preliminary injunction that was only in effect for several days before another court order reversed it again, leaving us with whiplash. While our Texas clinics continued to provide abortions under 6 weeks until *Roe* was overturned, we never recovered.

28. Now, our remaining clinics in Virginia and other states where abortion remains legal are facing extreme destabilization to patient care once again. First, on April 7, a district court in Texas issued an order saying that mifepristone could no longer be used anywhere in the country and gave the FDA only a week to seek emergency appeals. We immediately worked to develop protocols for non-mifepristone medication abortion protocols. But that same day, a district court in Washington issued an order requiring the FDA to maintain the status quo for

mifepristone but only in select states. While most of the states where WWH operates were included in that order, Virginia was not. We were left to figure out how, if at all, our use of mifepristone for patients in Virginia would need to differ from the rest of the country.

29. Then on April 12, the Fifth Circuit put part of the Texas order on hold. The Fifth Circuit's order only added to the confusion, as it said that while mifepristone could still be used, the FDA's changes to the REMS from 2016 onward were no longer in effect. Presumably this meant the court intended us to go back in time and use non-evidence based, outdated protocols for medication abortion. But did this apply to our clinics nationwide, or only in Virginia? We were still scrambling to make sense of this order when, hours before it was set to take effect, the U.S. Supreme Court put it on hold, but only for a couple days. That order was extended until April 21, 2023.

30. For our leadership and staff, the last few weeks have been extremely disruptive. We have devoted significant time to developing multiple new protocols that we do not know if we will ever need to use. We have re-written clinic procedures and patient consent forms. We have tried to prepare staffing for increased demand for procedural abortions and increased need for after-hours call. We have been doing our own medical research, reading studies to help inform new policies and procedures. When the Fifth Circuit's order came out, we also had to start looking for paperwork we haven't used in a decade and that may no longer exist. We have clinicians who have only ever worked in our virtual program and clinics that no longer have the equipment to comply with the 2016 REMS. In one week, we had four separate all staff meetings. All of this takes time, energy, and resources. This is time that is taken away from patient care.

31. Our patients are suffering too. We are seeing an increased call volume from confused and even panicked patients: many patients think that medication abortion is already

banned, and others are understandably confused about whether or not their appointments have been canceled. Pregnant people are scared that their rights are already gone, again.

32. We are also seeing an increased demand for procedural abortions because patients think that medication abortion is already banned. This is particularly challenging for clinics to manage because post-*Dobbs*, with abortion entirely banned in 13 states, there are many fewer clinics able to absorb the demand for procedural abortions. Telehealth has been instrumental in allowing clinics to meet the demand for abortions, and estimates indicate that after *Dobbs*, abortions provided via telehealth increase 137%.[1]

33. Throughout this dizzying time, our clinicians and staff—none of whom are party to any of the existing litigation—have been left to make sense of conflicting court orders, explain them to patients, and find some way to continue on with quality, evidence-based patient care. Neither we nor our patients have had any say in the matter. As a longstanding abortion provider, I know that regulatory interference with patient care creates chaos, and that chaos is by design.

34. The disruptions and constant instability have been extremely damaging to the emotional wellbeing of the abortion healthcare taskforce. As abortion bans took effect nationwide, our staff in Virginia and elsewhere watched their colleagues in Texas lose their jobs after decades of dedication to providing abortion care. Now they wonder if they will be next.

35. At base, the medically unnecessary REMS restrictions, with their burdens on patients and clinicians, and the unfounded safety concerns they have generated, have significantly contributed to the chaos surrounding medication abortion provision.

[1] *#WeCourt Report*, Society of Family Planning (April 11, 2023), https://www.societyfp.org/wp-content/uploads/2023/03/WeCountReport_April2023Release.pdf.

Restricting Certified Mifepristone Prescribers to Physicians Only

36. Whole Woman's Health clinics currently employ and seek to employ advanced practice clinicians ("APCs") like nurse practitioners to provide medical services within their scope of practice, including administering or dispensing medication abortion. WWH of Alexandria, for example, only has physicians providing abortion Thursday through Saturday, so employing APCs allows the clinic to offer abortions for the rest of the week and frees up clinic space and resources for later abortion cases over the weekend. Yet under the physician-only certified prescriber requirement in the REMS for mifepristone, APCs can only provide mifepristone if done so under a certified prescriber and supervisory relationship. The FDA eliminated this requirement of the REMS in 2016 precisely because it was overly onerous and medically unnecessary.

37. Reinstating the physician-only certified prescriber requirement would complicate WWH's operations and recruiting of APCs with no benefit to patient care.

Banning Mifepristone by Mail

38. Telehealth has been a significant innovation in the provision of medical care, particularly to underserved and rural communities. The COVID-19 pandemic in particular led to significant improvement in patient access to and comfort with using telehealth services for any number of medical conditions. The optimal use of telehealth in the provision of abortion care, however, depends on the ability to dispense mifepristone remotely. Because the REMS still prohibit clinicians from writing a prescription for mifepristone, the only remote option for distribution of mifepristone is by mail.

39. If clinicians are required to dispense mifepristone in person, their patients are forced to travel to the clinic to pick up the medication, even if doing so requires significant travel and other logistical challenges.

40. After temporarily suspending the in-person requirement during the COVID-19 pandemic, the FDA updated the REMS in January of 2023 to permanently eliminate the requirement.

41. For WWH and our patients, this change in the REMS was huge. It allowed us to build out our telehealth practice and begin working with a mail order pharmacy to dispense mifepristone.

42. In turn, WWH's Virtual Program has been critical in allowing WWH to meet the demand for abortions from patients traveling from states where abortion is now banned. The program allows us to free up clinic space and appointment times for patients who either prefer procedural abortion or who need a procedural abortion, particularly patients traveling from out of state. At our clinics nationwide, we are seeing many more patients pushed later into pregnancy by abortion bans in their states, so we have been forced to find ways to serve more patients in need of second trimester abortions. Telehealth has been instrumental in that effort.

43. For example, expanding our virtual program to New Mexico allowed us to continue seeing patients traveling from Texas, even after our Texas clinics were forced to close. Even though we now have a clinic site in New Mexico, almost all of our patients seeking telehealth in New Mexico travel from out of state. The virtual program allows patients to reduce their travel time and expense and helps ease clinic congestion. This is particularly important

because the New Mexico clinics, who have been inundated with patients traveling from out of state since *Roe v. Wade* was overturned, often have a 3-week wait for appointments.[2]

Harm of the 2023 REMS

44. While the FDA's decisions to follow at least some of the science and remove many onerous and medically unnecessary restrictions on mifepristone over the years has helped our patient access care, barriers still remain. The requirements that providers and pharmacies be certified and patients and providers sign agreements do nothing to improve patient care. Rather, they significantly add to the operational and logistical burden of administering and dispensing medication abortion, reduce the pool of clinicians we can hire to provide medication abortion, and incorrectly leave some with the impression that mifepristone is less safe than it is. Critically, these requirements effectively prevent a physician from writing a prescription for mifepristone that would allow a patient to pick the drug up at their local pharmacy.

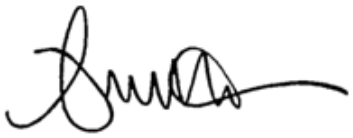
45. We have decades of evidence demonstrating that medication abortion with mifepristone is safe, effective, and preferable for many patients. In our experience, patients prefer medication abortion for a variety of reasons, including: it is less medicalized; it is more private and allows patients, particularly those in abusive relationships, to play off their abortion as a miscarriage to protect their own safety; it can be done on the patient's schedule; it allows the patient to have more control; it is more appropriate for some survivors of sexual assault; and it is medically indicated for some common health conditions like fibroids or obesity and certain kinds of cervical anatomy.

[2] *See* Elise Kaplan, *'They're Fearful': What New Mexico Abortion Providers are Seeing as Their Patient Numbers Soar*, Albuquerque Journal (Mar. 25, 2023), https://www.abqjournal.com/2585163/theyre-fearful-what-new-mexico-abortion-providers-are-seeing-as-their-numbers-of-patients-soar.html.

46. I think it is high time that the FDA eliminated the REMS altogether. It is the evidence-based and patient-centered thing to do.

47. At a minimum, it is critical to the care of our patients, the sustainability of our medical clinics, and the retention of our clinicians and staff that the 2023 REMS be maintained while this and other litigation proceeds.

Dated: May 8, 2023



Amy Hagstrom Miller

EXHIBIT 52

Declaration of Connie Cantrell

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF CONNIE CANTRELL

I, Connie Cantrell, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am the Executive Director of Cedar River Clinics, an organization that provides direct patient services, including birth control and abortion, and works to preserve and ensure access to reproductive and sexual healthcare. As Executive Director, I am responsible for an organization with four clinic locations and a telemedicine program in Washington State. I have served in this role since 2017. Before that, I spent about a decade as Cedar River Clinic's Director of Operations and served for approximately 14 years as a Clinic Manager in Cedar River's Yakima clinic. I have also held the role of Certified Health Assistant, and Surgical Tech, and briefly served as a volunteer when I first joined Cedar River Clinics in 1992. All told, I have been with Cedar River Clinics for more than thirty years.

3. Early in my career at Cedar River Clinics, I received training as a Certified Health Care Assistant. I worked under the supervision of Attending Physicians to provide direct patient care for patients seeking abortions, including providing patient counseling, pre and post abortion care, and assisting in abortion procedures. I am also familiar with medication abortions.

4. Cedar River Clinics has locations in Renton, Seattle, Tacoma, and Yakima. Our reproductive health care clinics offer first and second trimester

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abortions, birth control, STI testing and treatment, cancer screenings, annual exams, and more. We have a LGBTQ wellness program which includes gender affirming care for transgender/non-binary patients. We offer both in-clinic and telemedicine services and are a member of the Reproductive and Sexual Health Program with the Washington Department of Health.

5. Cedar River Clinic was founded in Yakima in 1979 with subsequent locations being added when provider owners retired or wanted to close. Expanding abortion access is one of our priorities but we had to make the difficult decision to close our Yakima clinic in 2010. However, after hearing from patients traveling to us from Eastern Washington about the increasing wait times, we did a community needs assessment which led to our decision to reopen our Yakima location. Due to COVID, we expedited to begin our reopening as a telemedicine satellite site and last year, we opened for in-person care. Due to the reversal of *Roe v. Wade*, we expedited the plans to further expand the clinical space in Yakima so we can reopened fully to offer abortion procedures in March of 2023.

6. When the Yakima clinic resumes providing surgical abortions in March 2023, it will be only one of a small handful of full-service abortion clinics in Eastern Washington.

The Impact of *Dobbs*

7. For nearly 45 years, Cedar River Clinics had been providing first and second trimester abortion to individuals from across Washington State and

those traveling from out of state or internationally. Many of those patients had to travel due to restrictive laws. Since the *Dobbs v. Jackson Women's Health Organization* decision in June 2022 and subsequent abortion bans, Cedar River Clinics are experiencing a rising tide in the volume of individuals coming to Washington from other states to seek an abortion. It is not limited to our region; we are serving patients from across the country especially the South and Midwest who are being impacted by the abortion bans in their states.

8. Based on my own and my staff's observation, in the post-*Dobbs* landscape, it has also been harder for individuals to understand their options when seeking abortion care. There is significant confusion among individuals, especially individuals traveling to Washington from states criminalizing abortion or restricting abortion access, regarding what is legal and what consequences they may face in their home jurisdiction. At Cedar River Clinics, we make it a priority to educate patients and inform them of their rights. Because of *Dobbs* we are seeing an increasing need to devote resources to patient education, reassurance, and outreach.

9. We have also seen an escalation in protesters since *Dobbs*. This includes protesters blocking patients from driving up to our clinics and harassing staff, patients, and their support people at the clinic entrance. In addition to the mental and emotional burden this imposes, this means clinics need to devote more resources to managing this issue and provide security.

The Importance of Mifepristone

10. Mifepristone is one of a two-drug regimen that is the standard of care for medication abortions and miscarriage management. Medication abortions have become increasingly prevalent in Washington in the last several years. Cedar River Clinics offers medication abortion in-clinic and through telemedicine. Today, medication abortions make up approximately 40% of all the abortions Cedar River Clinics perform.

11. If mifepristone is removed from the market, it will have a devastating impact on individuals trying to access abortion. If patients are unable to access mifepristone, their options may only be a misoprostol-only abortion or surgical abortion. Returning to a one-drug, misoprostol-only protocol for medication abortion and miscarriage management will harm patients. Misoprostol is less effective and has more severe side effects. Moreover, misoprostol-only abortions typically require more doses over a longer period of time, and thus take longer to complete than abortions using a combination of mifepristone and misoprostol.

12. Surgical abortion will be the other option for patients who do not have access to mifepristone. There are a multitude of reasons why a patient may prefer a medication abortion to surgery including personal preference and matters of privacy and safety. Medication abortion offers greater privacy for patients, some of whom may fear being seen by community members or by an abuser if

forced to visit a known abortion clinic. Patients often prefer not to face protesters. Other individuals may not have the ability to travel to a clinic location for a variety of reasons, including being unable to take time away from work, childcare concerns, or to afford the cost of transportation. Although we subsidize care and abortion funds help as much as possible, the cost of surgical abortion is also prohibitive for many patients.

13. Clinics would also very likely see a higher number of second trimester surgical abortion cases if mifepristone is removed from the market. Arranging time off work, arranging childcare, and making travel plans for a surgical abortion takes time and could push some abortions into the second trimester.

14. For clinics themselves, surgical abortions require more time, money, and resources for staff, and to subsidize patient care. This means clinics would serve fewer individuals and abortion would become less accessible for all.

I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 21 day of February, 2023, at Seattle, WA.

Connie Cantrell

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EXHIBIT 53

Declaration of Paul Dillon

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First Assistant Attorney General
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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF PAUL DILLON IN SUPPORT OF MOTION FOR PRELIMINARY INJUNCTION

ATTORNEY GENERAL OF WASHINGTON
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I, Paul Dillon, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I am the Vice President for Public Affairs of Planned Parenthood of Greater Washington and Northern Idaho (PPGWNI). I have worked for PPGWNI since 2015, and have been in my current role since 2018.

3. In my role as Vice President of Public Affairs for PPGWNI, I am responsible for managing outreach in support of PPGWNI's mission to providing exceptional health care services, honest education and fearless advocacy. I represent PPGWNI in the communities we serve and within the affiliate as an executive leader.

A. Access to Abortion in Washington

4. PPGWNI operates 11 clinics throughout central and eastern Washington, with locations in Spokane, Spokane Valley, Pullman, Walla Walla, Moses Lake, Sunnyside, Pasco, Kennewick, Wenatchee, Yakima, and Ellensburg. Each clinic offers medication abortions. Procedural abortions are only available at our clinics in Spokane, Kennewick, and Yakima.

5. Washington has a strong legacy of protecting abortion rights. But rights aren't rights without access. In central and eastern Washington access to abortion is quite limited.

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6. Of the 20 central and eastern Washington counties within PPGWNI's territory, only nine have abortion providers to my knowledge.[1] Because a majority of counties do not have abortion providers, and because those that do have only very few abortion providers, many pregnant people in central and eastern Washington have to travel a long way for medical care. For example, if someone lives in Republic, Washington, their nearest clinic providing abortion care is PPGWNI's clinic in Spokane, approximately three to three-and-a-half hours away.

7. PPGWNI's clinics are all located in medically underserved communities. PPGWNI sees a high percentage of patients on Medicaid. In central Washington in particular, PPGWNI serves a large population of monolingual Spanish-speakers, many of whom are migrant farmworkers. Access to abortion care is still very limited for these and other populations PPGWNI serves.

B. The Impacts of *Dobbs*

8. The Supreme Court's *Dobbs* decision overturning *Roe v. Wade* has created significant barriers for PPGWNI's efforts to provide abortion care, even as abortion remains legal in Washington.

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[1]The 11 central and eastern Washington counties without abortion providers to my knowledge are: Klickitat, Okanogan, Douglas, Ferry, Stevens, Pend Oreille, Adams, Lincoln, Columbia, Garfield, and Asotin Counties.

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9. With three of our clinics (Spokane, Spokane Valley, and Pullman) so close to the border, PPGWNI has long seen patients from Idaho. But since *Dobbs*, we have seen a significant increase in out-of-state patients.

10. In January 2023, PPGWNI saw an increase of 25% in total abortion patient visits compared to January 2022. We saw a 75% increase in Idaho patients from January 2023 compared to January 2022. This includes a 36% increase for procedural abortion patient visits and 90% increase for medication abortion visits from Idaho.

11. Our clinics in Pullman and Kennewick saw the biggest changes. In our Pullman clinic, we now have an outright majority of patients—53% in 2022 and likely higher in 2023—coming from Idaho. This is up from 39% in 2021.

12. Further, with the closure of PPGWNI's Boise clinic, we have started to see an influx of out-of-state patients at our Kennewick and Walla Walla clinics. These clinics have not historically treated many out-of-state patients, but they are now the closest clinics for many people in southern Idaho.

13. Since *Dobbs*, We have also started to see patients come from as far away as Texas and Florida.

14. This increase in patient volume has led to longer wait times to see providers in PPGWNI's clinics including up to three weeks for smaller sites like Wenatchee and Walla Walla. These longer wait times can have serious repercussions because abortion is a time-sensitive service. In many cases, a

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three-week wait may put someone past the point where a medication abortion is possible.

C. The Importance of Mifepristone

15. As I noted above, all of PPGWNI's clinics provide medication abortions using mifepristone. Mifepristone is a very important medicine for PPGWNI's patients and providers.

16. Lack of access to mifepristone has negative consequences for patients seeking abortion as well as providers.

17. When patients are not able to access mifepristone, their options are misoprostol-only abortions or procedural abortions.

18. Based on many conversations with PPGWNI providers, I am aware that misoprostol-only medication abortions lead to more severe side-effects like bleeding, cramping, flu-like symptoms, and nausea. Moreover, misoprostol-only abortions typically require more doses of misoprostol over a longer period of time, and thus take longer to complete than mifepristone/misoprostol abortions. This means that a patient undergoing a misoprostol-only abortion is likely to spend additional days in discomfort and cramping until their abortion is complete.

19. Procedural abortion is the other option for patients who do not have access to mifepristone. For patients who, for whatever reason, are unable to obtain mifepristone within the first 10 weeks of pregnancy, procedural abortion

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may be their only option. While procedural abortion is extremely safe and effective, it has several disadvantages compared to medication abortions.

20. Unlike mifepristone, which is available at each of PPGWNI's 11 clinics, including via telehealth appointments, and can be mailed to patients in Washington, PPGWNI can only provide procedural abortions at three of its locations. Consequently, patients who need procedural abortions, but live far away from PPGWNI's clinics that provide it, may face significant travel barriers. And due to the lesser availability, patients requiring procedural abortions generally face longer wait times for appointments, which can lead to significant stress and other complications.

21. Procedural abortion is also considerably more expensive—both for PPGWNI and patients. Medication abortion costs $700. For procedural care, if gestation is 19 weeks to 21 weeks, the cost can range between $1,450–$1,850. Beyond the cost of the procedure itself, patients undergoing procedural abortions often have to pay for things like travel and lodging, neither of which is necessary for a patient who simply receives mifepristone in the mail.

22. Furthermore, medication abortions are simply preferable to many patients. A patient undergoing a procedural abortion must come into the clinic, undergo a medical procedure, spend time in the recovery room, etc. By contrast, a patient undergoing a medication abortion can be in the comfort and safety of

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home, in a supportive environment, with Netflix and a heating pad, if they so choose.

D. The 2023 Mifepristone REMS

23. While we were grateful for the removal of the in-person requirement with the FDA's recent updates to REMS for mifepristone, it still created an unnecessary pharmacy certification requirement that it does not impose for other, equally or less safe, medications. This creates additional barriers to access for patients who are travelling to our health centers from out of state and need time-sensitive care. Unfortunately, the updated REMS also retains longstanding requirements that providers be specially certified in order to prescribe mifepristone and that patients sign a special form in order to receive their prescription, a challenge at a time of provider shortages throughout central and eastern Washington. Permanently removing the REMS in its entirety is critical to reducing the disproportionate harms of abortion restrictions.

E. Threats to Abortion Providers

24. Abortion remains highly stigmatized throughout much of the area PPGWNI serves. PPGWNI clinics—including our providers and patients—have been subject to violence and harassment.

25. In 1996, PPGWNI's Spokane Valley clinic was bombed by anti-abortion extremists. In 2015, an arsonist set fire to PPGWNI's clinic in

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Pullman. In 2020, PPGWNI's Spokane clinic received a bomb threat. In 2021, PPGWNI's Spokane Valley clinic had its windows smashed.

26. PPGWNI providers and patients are also subject to routine harassment and intimidation from anti-abortion activists at our clinics. Recently, protestors associated with the "Church at Planned Parenthood" have gathered at PPGWNI clinics in an effort to disrupt clinic operations. These protesters have yelled at and verbally harassed patients, and have frequently interfered with clinic operations, including by blocking driveways and sidewalks. One group member in Yakima followed a PPGWNI provider to their home.

27. In 2021, a judge on the Spokane County Superior Court concluded that the group violated a Washington law prohibiting interference with health facilities and permanently enjoined the group from interfering with PPGWNI's clinic operations. Earlier this year the Court ordered the group to pay $110,000 in damages to PPGWNI, as well as attorneys' fees. Even so, the group has continued its protests and communicated to us that they intend to come back even harder.

28. This is part of a pattern since *Dobbs*, in which PPGWNI has seen protests intensify. According to our security data, protest activity post-*Dobbs* is 50% higher than it was in 2021.

29. We have also seen these efforts to disrupt our operations spread to clinics where they did not previously occur. For example, we did not normally

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have protests at our Wenatchee clinic, but since *Dobbs*, we have seen regular protests there.

30. In addition to the harassment and violence, PPGWNI routinely faces cybersecurity threats from hackers trying to obtain information about patients and providers. Most commonly, we receive phishing emails that seek to obtain patient records and provider addresses. Because of the heightened risk of cybsersecurity attacks, every PPGWNI staff member has to undergo annual IT security training.

31. Due to these various threats to PPGWNI's clinics, providers, and patients, we have had to devote considerable resources to security and patient privacy.

32. All PPGWNI clinics have security cameras and employ security guards to be on-site whenever the clinics are open. Clinics have locking vestibules known as "man traps" to ensure unauthorized people cannot enter the clinics. The clinics are also now equipped with bulletproof glass, following the incident in Spokane Valley in which the clinic's windows were smashed.

33. PPGWNI also maintains rigorous standards around patient privacy. We prohibit filming or recording equipment on site, maintain secure waiting areas and a rigorous check-in process, require providers to badge in and escort patients, etc. Nonetheless, we still face issues with protesters trying to film patients and providers, record license plates, and otherwise harass patients and providers.

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I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

DATED this 17th day of February 2023, at Spokane, Washington.

Paul Dillon

PAUL DILLON
Vice President of Public Affairs
Planned Parenthood of Greater
Washington and Northern Idaho

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EXHIBIT 54

Declaration of Cynthia Harris

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UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF WASHINGTON

STATE OF WASHINGTON, et al., Plaintiffs, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, et al., Defendants.	NO. 1:23-cv-03026 DECLARATION OF CYNTHIA HARRIS

I, Cynthia Harris, declare as follows:

1. I am over the age of 18, am competent to testify as to the matters herein, and make this declaration based on my personal knowledge.

2. I have worked in the Sexual and Reproductive Health field for almost 30 years - 7 years at the clinic level and 22 years at the state level. I have been the manager of the Sexual and Reproductive Health Program at the Washington State Department of Health for 10 years.

3. As manager of the Department of Health's Sexual and Reproductive Health Program, my responsibilities are to ensure access within available funding to contraceptive services, STI testing, STI treatment and other sexual and reproductive health services including abortion through contracts with providers throughout Washington State.

4. The most-recent year for which the Washington State Department of Health has finalized abortion-care data is 2021. In 2021, there were 15,968 abortions among Washington residents, out of 100,340 reported pregnancies. In addition to abortions among Washington residents, 998 abortions were provided to non-residents who traveled from out of state. Non-residents seeking abortion care in Washington came from 41 states, as well as Guam and Canada, with the majority coming from Idaho (406), Oregon (330), and Alaska (51).

5. In 2021, 59% of the abortions provided in Washington were medication abortions.

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6. The total number of Washington facilities that reported providing abortions in 2021 is 46. Of those facilities, 37 provided five or more abortions.

7. DOH's Sexual and Reproductive Health Program contracts with 6 agencies that have 34 of the 46 clinics that provide abortions in Washington. These contracts are part of DOH's public health mission to improve equitable access to affordable, quality abortion care services for low-income and underserved patients in Washington. The six agencies DOH contracts with are: Planned Parenthood Great Northwest, Hawai'i, Alaska, Indiana, Kentucky; Planned Parenthood of Greater Washington and North Idaho; Planned Parenthood Columbia Willamette; Mount Baker Planned Parenthood; Cedar River Clinics; and Equinox Primary Care.

8. Of the 34 DOH-contracted abortion clinics, 22 are located in western Washington and 12 are located in eastern Washington (east of the Cascade Mountains). Of the 12 contracted clinics in eastern Washington, 11 are operated by Planned Parenthood Greater Washington Northern Idaho, and one is operated by Cedar River Clinics. Outside of these two important partners, DOH has not located providers with the resources, capacity, and willingness to provide abortion care services in the eastern part of the State.

9. All of the 34 DOH-contracted registered abortion clinics in Washington provide medication abortions, with 31 offering medication abortions via telehealth.

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10. Twelve of the 34 DOH-contracted registered abortion clinics also provide procedural abortions. Of these 12 clinics that provide procedural abortions, 9 are in western Washington, all located on the I-5 corridor. Three DOH contracted abortion clinics provide procedural abortions in eastern Washington, with one clinic in Kennewick, one clinic in Spokane, and one clinic in Yakima. An additional procedural abortion site will open in Yakima in March 2023.

11. Exhibit 1 is a map showing the 20 out of Washington's 39 counties that have registered abortion clinics that contract with DOH. Abortion service access points are saturated on the western side of the state while sites in the eastern and southern parts of Washington are most likely to serve patients from Idaho and Oregon respectively based on geographic location. Clinics offering both medication and procedural abortion are located further away from each other in eastern Washington, which can cause residents of those counties to travel longer distances to access care, especially depending on appointment availability.

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I declare under penalty of perjury under the laws of the State of Washington and the United States of America that the foregoing is true and correct.

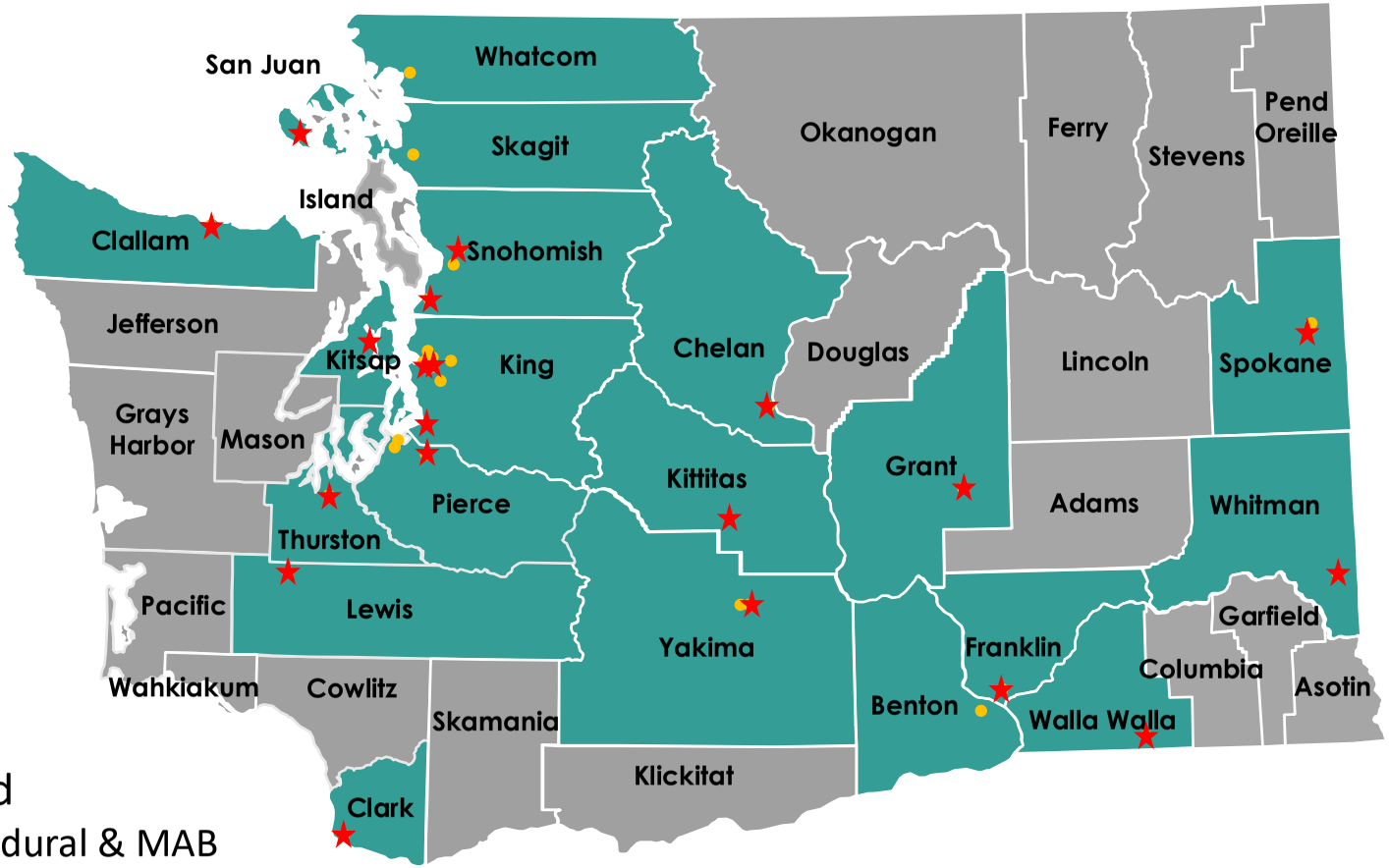
DATED this 21st day of February, 2023, at Mabton, Washington.

Cynthia Harris

CYNTHIA HARRIS

Exhibit A

Washington State Sexual & Reproductive Network Abortion Service Sites



Legend

- Procedural & MAB
- ★ MAB Only

App. 000940

EXHIBIT 55

Two years after Missouri banned abortion, navigating access still involves fear, confusion – Missouri Independent

HEALTH CARE

2 years after Missouri banned abortion, navigating access still involves fear, confusion

The U.S. Supreme Court overturned the constitutional right to an abortion two years ago. Since then, thousands of Missourians sought other ways to access the medical procedure

BY: **ANNA SPOERRE** - JUNE 24, 2024 5:55 AM

The message "You are not alone, support is here" is painted on the window of the Planned Parenthood Great Plains on Friday in Overland Park, Kansas (Anna Spoerre/Missouri Independent).

When Missouri outlawed abortion two years ago, Nicole was far more worried for her grown children than for herself.

It had been two decades since she last gave birth, when she suffered a serious stroke during labor followed by severe postpartum depression. She was outraged that the U.S. Supreme Court overturned the constitutional right to abortion, but pregnancy was in Nicole's past.

That changed a couple weeks later, when her IUD failed.

"Are you kidding me?" she recalls thinking, looking around at the life she and her husband had built together in southwest Missouri.

In her 40s and living in a state where virtually every abortion is now banned, Nicole – who asked to only be identified by her middle name for fear of prosecution – was among the first of thousands of

Missouri women forced to navigate abortion access in a post-Roe world.

On June 24, 2022, Missouri became the first state in the country to respond to the U.S. Supreme Court's landmark ruling in Dobbs v. Jackson Women's Health, striking down Roe v. Wade and the constitutional right to an abortion. The Republican-run state quickly enacted its trigger law banning all abortions with limited exceptions in cases of medical emergencies.

In the two years since, countless women like Nicole have faced already tough decisions made more excruciating by having to find discreet ways to manage their own health or travel far from home for care.

Missouri already had some of the strictest abortion regulations in the country, pushing most women seeking access to the procedure out of state. But the end of Roe raised the stakes, leaving women in Missouri – which already has some of the highest maternal mortality rates in the country – fearful that in the most extreme cases, the ban could mean their death.

A recovery room at the Planned Parenthood Great Plains office is pictured on Friday in Overland Park, Kansas (Anna Spoerre/Missouri Independent).

Last year, approximately 2,860 Missourians traveled to Kansas last year for abortions, and 8,710 traveled to Illinois, according to the Guttmacher Institute, a reproductive rights research group that closely tracks abortion data. But they made up only about 10% of the total abortion patients in each state.

After Dobbs, Missourians' access to care in states like Kansas and Illinois became precarious as abortion bans became more widespread.

"In a matter of months, we started serving patients from Texas and Arkansas and Oklahoma," Emily Wales, CEO and president of Planned Parenthood Great Plains, said of the time immediately

following the Dobbs decision. "Missourians had to really compete for too few appointments."

The longer wait times at clinics and barriers to traveling for abortions has led Missourians to increasingly consider self-managed abortions.

That includes Nicole, who received an envelope at home marked with international postage containing Mifepristone and Misoprostol after consulting an online doctor she found through Plan C, a nonprofit that helps people find providers.

Missourians navigate abortion access after Dobbs

For Nicole, the decision to end her most recent pregnancy was simple. To continue felt unsafe, she said, and she and her husband didn't want to start over raising a child.

But the conversations that followed were kept strictly between the husband and wife.

With pervasive uncertainty around whether or not women could be prosecuted for self-administering medication abortions in Missouri, the stakes are higher than ever for those trying to end unwanted or medically complicated pregnancies.

It's why Nicole didn't tell her pastor at church. She didn't tell friends or family. Nicole didn't even tell her gynecologist, fearing she would be reported by someone in their corner of the state where anti-abortion messaging proliferates billboards, bumper stickers and handwritten signs staked into yards.

Ultimately, Nicole couldn't imagine fleeing her state for the procedure. She wanted to be home.

"I felt really angry that I would have to leave my community," she said. "It's not a shameful thing, it's a procedure. It's a medical health care procedure."

In the six months after the Dobbs decision, the number of self-managed medication abortions rose by more than 26,000 across the U.S. according to a study published in JAMA, the American Medical Association's journal.

While medication abortions are overall very safe, effective and approved by the FDA to end pregnancies up to 10 weeks, there is some risk associated with any medication. Self-managing an abortion alone, without a local medical provider's guidance, can be nerve-wracking.

In the unlikely situation that Nicole started hemorrhaging, she and her husband mapped out the closest Kansas hospital that would have the level of care they needed.

When the time came, they both took a day off work and snuggled on the couch. Nicole pressed a heating pad to her abdomen to soothe the cramps, which she described as similar to period pains. Then came the relief.

After the abortion, her husband got a vasectomy. She kept the IUD. Despite their precautions, sex is now accompanied by paranoia as Nicole counts down the days to her period each month.

She ordered extra abortion medication in case anyone she knows might need it. And despite the nearly two years since her abortion, Nicole said she still can't shake the absurdity she felt hunkering down in her home that day.

"I make decisions for myself every day, and I make good decisions," she said. "The audacity that people think I can't make the best healthcare decisions for myself – it's hard for me to put into words how upsetting it is."

'I am desperate'

Stories of women desperate to end their pregnancies proliferate the internet.

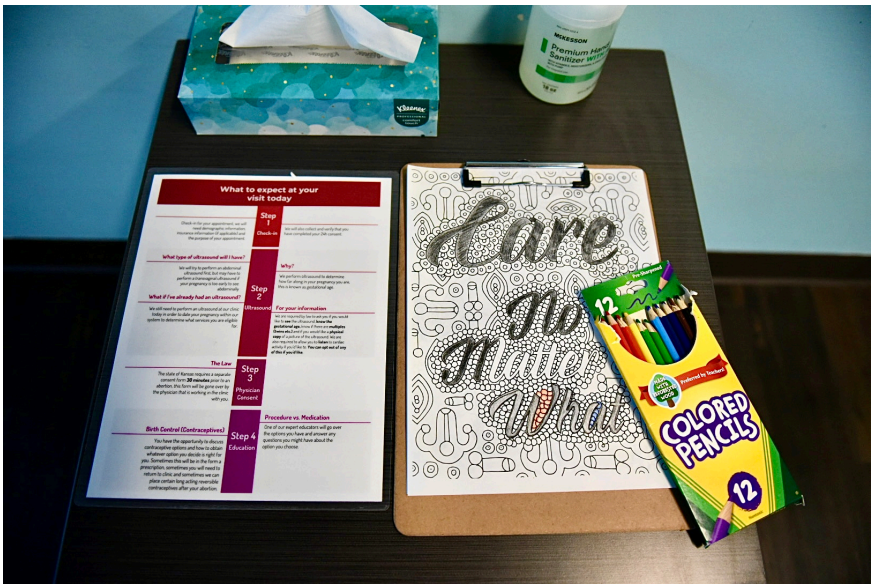
Reddit is increasingly a gathering place for those seeking answers and assurance. Many of the posts — all anonymous — illustrate how terrified many Missourians are.

In one post from mid-June, a 23-year-old woman from Missouri feared she was pregnant by her abusive boyfriend but didn't have the money to travel for an abortion.

"I will drink an entire bottle of vodka if I have to idc," she wrote. Other anonymous users quickly took to the page to offer other solutions.

In a 2023 post, someone inquired about getting an abortion for their pregnant 15-year-old sister in Missouri without parental consent.

"This experience is causing her to have suicidal thoughts, crippling anxiety, and extreme depression," the user wrote. "All of which she already had before this. I need help. I am desperate. I do not want to lose my baby sister."



Instructions on what to expect during a visit to Planned Parenthood Great Plains sits on a desk in the waiting room on Friday in Overland Park, Kansas (Anna Spoerre/Missouri Independent).

Even for those who work in abortion-rights advocacy, navigating an abortion post-Roe is anxiety-inducing.

Maggie Olivia first got pregnant while living in St. Louis in 2020. She was on birth control at the time.

Because of Missouri's "targeted regulation of abortion providers" laws, including mandatory pelvic exams for medication abortions and 72-hour waiting period between the initial appointment and a surgical abortion, she was encouraged to go to a Planned Parenthood in Illinois.

It was clinic escorts with Abortion Action Missouri who guided Olivia into her appointment just across the Mississippi River and reassured her ahead of the procedure. She was so moved by their kindness that Olivia went on to volunteer with the group, and now serves as a senior policy manager with the abortion-rights group.

In the months after the Dobbs decision, Olivia, like many in abortion advocacy work, was navigating the ever-changing landscape of abortion access. At the same time, Olivia said she was mistakenly denied her birth control prescription by a pharmacist after switching contraceptive methods.

When a pregnancy test came back positive several weeks later, Olivia's first call was to her boss, who she said offered immediate support and guidance.

"But even that close proximity to the reality of the crisis doesn't make being pregnant when you don't want to be any less horrifying," she said.

Unlike with her first pregnancy, Olivia decided not to tell her health care providers in Missouri.

But after ending up in the emergency room for unrelated reasons, her pregnancy was noted in her records. Months later, Olivia said she was denied access to an unrelated medication because her medical records said she was pregnant, compounding the fear she already had of being punished in some way for having an abortion, however legal, in Illinois.

"It was very upsetting," Olivia said. "And I had thought that I had taken steps to be precautious."

When she had her second abortion at the same Illinois clinic from two years prior, she also had an IUD placed.

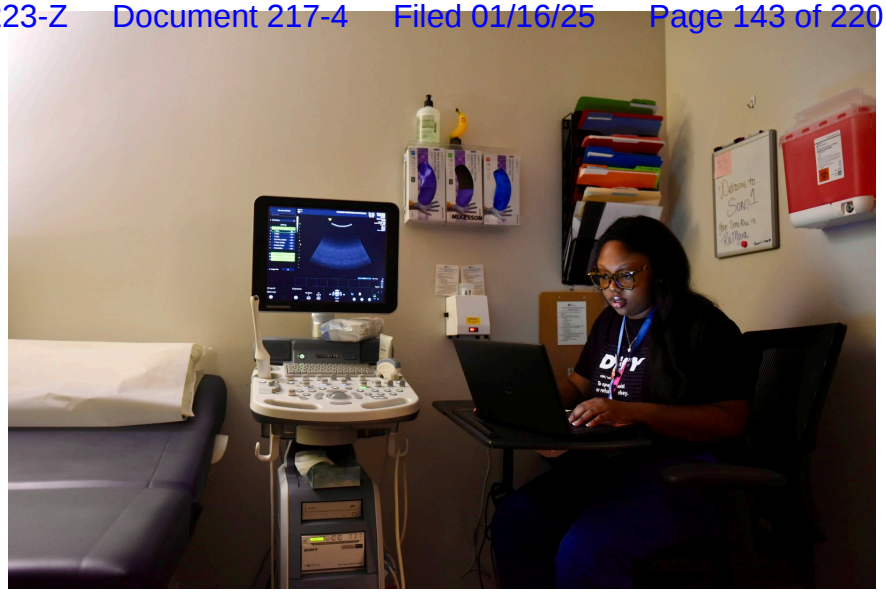
"Your access to abortion doesn't need to be attached to some traumatic, horrifying situation in of itself," Olivia said. "Being pregnant when you don't want to be is scary enough, is horrifying enough."

Higher stakes for providers

When a sonographer approaches Dr. Jennifer Smith, a St. Louis OB-GYN, her heart drops.

"Every time I look at a fetal ultrasound, it takes on new intensity and new anxiety," she said, concerned that her patient will have a diagnosis they can't be of help with in Missouri.

Missouri physicians are balancing medically complex pregnant patients with legal restrictions that could land them in prison for up to 15 years if they perform an abortion the state finds was unnecessary, and, therefore, illegal.



Ra'Maia Dillard, an ultrasound technician at Planned Parenthood Great Plains prepares to see a docket of 29 patients on Friday in Overland Park, Kansas (Anna Spoerre/Missouri Independent).

No providers have been prosecuted at this point, but the ways something could go wrong keep Smith up at night. So, too, does the future of not only maternal health care, but also motherhood in Missouri.

"Missouri women are afraid to be pregnant in Missouri," Smith said. "They are so worried that they might die while pregnant, or that they may get pregnant with a baby with anomalies and have no options because they live in Missouri."

While Smith is often helping women who want to be pregnant, a couple miles across the river in Illinois sits the regional logistics center for Planned Parenthood of the St. Louis Region and Southwest Missouri. There, three patient navigators help those trying to end their pregnancies.

Kenicia Page, the call center manager, said she saw a tremendous increase in callers from the West Palm Beach area, more than 1,100 miles south, when Florida's ban went into place on May 1.

Right now, she says the clinic receives about 100 calls a day.

They act as pseudo travel planners and financial aid counselors, helping book transportation and finding funding for patients.

Despite the comparative proximity, transportation can still be a headache for some Missourians, particularly those in rural parts of the state without access to public transportation like Greyhound buses or Amtrak, Page said. Sometimes, when the patient doesn't have a vehicle, nor access to public transportation or car rental services, their next best option is to rent a U-Haul to drive to their appointment.

But more often, Page said, she hears from Missourians trying to find and afford child care, or from minors who need a legal guardian to give consent for financial assistance. Some days Page still finds

herself breaking the news to Missouri callers that abortion is illegal within their state borders, and that they will likely have to take a multi-day trip to Illinois to get care.

Page recently spoke with a woman who was homeless and living in a hotel with her children. She had no child-care options, nor a place to stay after the procedure. Page's team helped connect the woman to funders who assisted with the day care fees and made sure she had a safe place to recover overnight in Illinois.

Their work is done when they get the final call or text from a patient saying they've returned home safely.

"It gives you that extra energy or extra push, determination, to continue to do what you do," Page said. "Because it is definitely making a difference."

Alison Dreith's hotline through Midwest Access Coalition, an abortion fund based in Illinois, used to serve a majority of Missouri clients. As of mid-June, only 26 of the total 1,052 callers this year were from Missouri. Now most of her calls come from Texas, Indiana and Tennessee as patients from red states crowd clinics in Illinois and Kansas.

"Every time a new state goes," Dreith said, "it has the ripple effect that reaches the Midwest."

The need for child care is a refrain for patients, particularly lower-income Missourians,traveling to Kansas overnight for the procedure, said Wales, with Planned Parenthood Great Plains.

The short drive from Kansas City to Wyandotte or Johnson counties in Kansas has expanded from a fissure to a canyon for some patients. Those requesting medication abortions are usually seen within a week, but patients needing in-clinic abortions can wait two or three weeks to be seen, Wales said.

"We have to explain that we may be close to you, but we are seeing patients from around the region," she said. "It doesn't make it easier, necessarily, to get an appointment."

Denise Baker, a reproductive health assistant at Planned Parenthood Great Plains prepares patient paperwork behind the clinic's front desk on Friday in Overland Park, Kansas(Anna Spoerre/Missouri Independent).

Wales said many patients are also coming to them later in gestational age, and increasingly with fetal abnormalities. This is a theme across the country, as patients work to find an appointment, save up money and arrange time off work.

Because of the increase in demand, Planned Parenthood Great Plains will soon start seeing patients for abortions in Pittsburg, making it the fourth Kansas clinic to offer the procedure. She hopes that will cut down on drive times for Missourians in regions including Joplin and Springfield.

Julie Burkhart, co-owner of Hope Clinic, an abortion provider in Granite City, Illinois, has seen the number of Missourians served at her clinic more than triple since 2019. But even so, the percentage of total patients from Missouri has gone from more than 60% to less than half as patients from 28 states made their way to her clinic near the Mississippi River last year.

Wait times hover between one and two weeks. In May, the clinic saw 732 abortion patients; 45 were from Missouri.

Funding needs have skyrocketed since Roe fell, and she's seen the number of Missouri patients seeking abortions in their second trimester increase to 17% this year. Before Roe, it was closer to 8% for all patients.

"With Roe falling, people who don't have to think about abortion access every day don't quite know where to look, who to call, who to talk to," Burkhart said. "It's put people in more desperate situations."

This story was corrected at 4:45 p.m. to accurately describe the nonprofit Plan C.

ANNA SPOERRE

Anna Spoerre covers reproductive health care. A graduate of Southern Illinois University, she most recently worked at the Kansas City Star where she focused on storytelling that put people at the center of wider issues. Before that she was a courts reporter for the Des Moines Register.

Missouri Independent is part of States Newsroom, the nation's largest state-focused nonprofit news organization.

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EXHIBIT 56

CVS and Walgreens plan to sell abortion pill mifepristone at pharmacies after FDA rule change

BREAKING NEWS

HEALTH AND SCIENCE

CVS and Walgreens plan to sell abortion pill mifepristone at pharmacies after FDA rule change

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KEY POINTS

Walgreens and CVS both plan to get certified to dispense the abortion pill mifepristone to patients in states where abortion remains legal.

The FDA dropped long-standing restrictions this week that prevented retail pharmacies from offering mifepristone.

Mifepristone has become a central flashpoint in the political battle over abortion at the state level in the wake of the Supreme Court overturning Roe v. Wade.

The two drugs used in a medication abortion, is displayed at the Women's Reproductive Clinic, which provides legal medication abortion
lexico, on June 15, 2022.

Robyn Beck | AFP | Getty Images

Walgreens and CVS will sell the prescription abortion pill mifepristone after the Food and Drug Administration this week dropped a long-standing rule that prevented drug stores from doing so.

The decision by the two largest drug store chains in the U.S. will significantly expand access to mifepristone in states where abortion is legal. The companies cannot offer the pill in states that have completely banned abortion in the wake of the Supreme Court decision that overturned Roe v. Wade.

The FDA on Tuesday changed its regulations to allow retail drug stores to dispense mifepristone so long as they complete a certification process. The agency dropped a long-standing rule that required patients to obtain the abortion pill in-person at clinics, hospitals and other certified health-care providers.

Walgreens plans to get certified and is working through the registration and training of its pharmacists to dispense mifepristone consistent with federal and state law, spokesperson Fraser Engerman said. CVS also plans to get certified in states where it is legal to do so, spokesperson Amy Thibault said.

This means patients in many parts of the U.S. will effectively be able to obtain mifepristone like other prescription medications, either in-person at a retail pharmacy or through the mail. Patients will still need to obtain their prescription from a certified health-care provider.

Mifepristone has become a central flashpoint in the political battle over abortion at the state level in the wake of the Supreme Court overturning Roe v. Wade. Several conservative groups have asked a federal court in Texas to overturn the FDA's approval of mifepristone.

Mifepristone is the most common way to terminate a pregnancy in the U.S. Some 51% of abortions were performed with mifepristone in 2020, according to the Centers for Disease Control and Prevention.

The FDA first approved mifepristone more than 20 years ago in 2000 as a method to terminate early pregnancies, but the pill long had strict regulations around how it could be dispensed to patients. Medical organizations such as the American College of Obstetricians and Gynecologists had long argued that those regulations lacked a scientific basis and were rooted in politics.

Mifepristone is approved to end a pregnancy through the 10th week. It is used in combination with another pill called misoprostol. Mifepristone stops the pregnancy from continuing and misoprostol induces contractions that empty the uterus.

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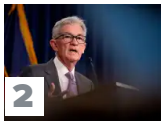

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EXHIBIT 57

In Washington state, pharmacists are poised to start prescribing abortion drugs - NPR

POLICY-ISH

In Washington state, pharmacists are poised to start prescribing abortion drugs

UPDATED MARCH 1, 2024 · 2:56 PM ET

By Patrick Adams

Mifepristone is a medication typically used in combination with misoprostol to bring about a medical abortion.

Soumyabrata Roy/NurPhoto via Getty Images

Update: On March 1, major pharmacy chains CVS and Walgreens announced they had been certified to begin dispensing mifepristone at select locations in states where abortion is legal. The effort described in this story would go a step further

than that, allowing pharmacists themselves to prescribe the abortion medication, without a physician.

Over the past several months, a handful of community pharmacies in states where abortion remains legal have begun to take advantage of a new rule that allows them to fill prescriptions for the abortion pill mifepristone. Prior to the rule change, which was finalized last January by the Food and Drug Administration, pregnant people had to get the drug directly from their doctor or by mail if using telemedicine, depending on the laws in their state.

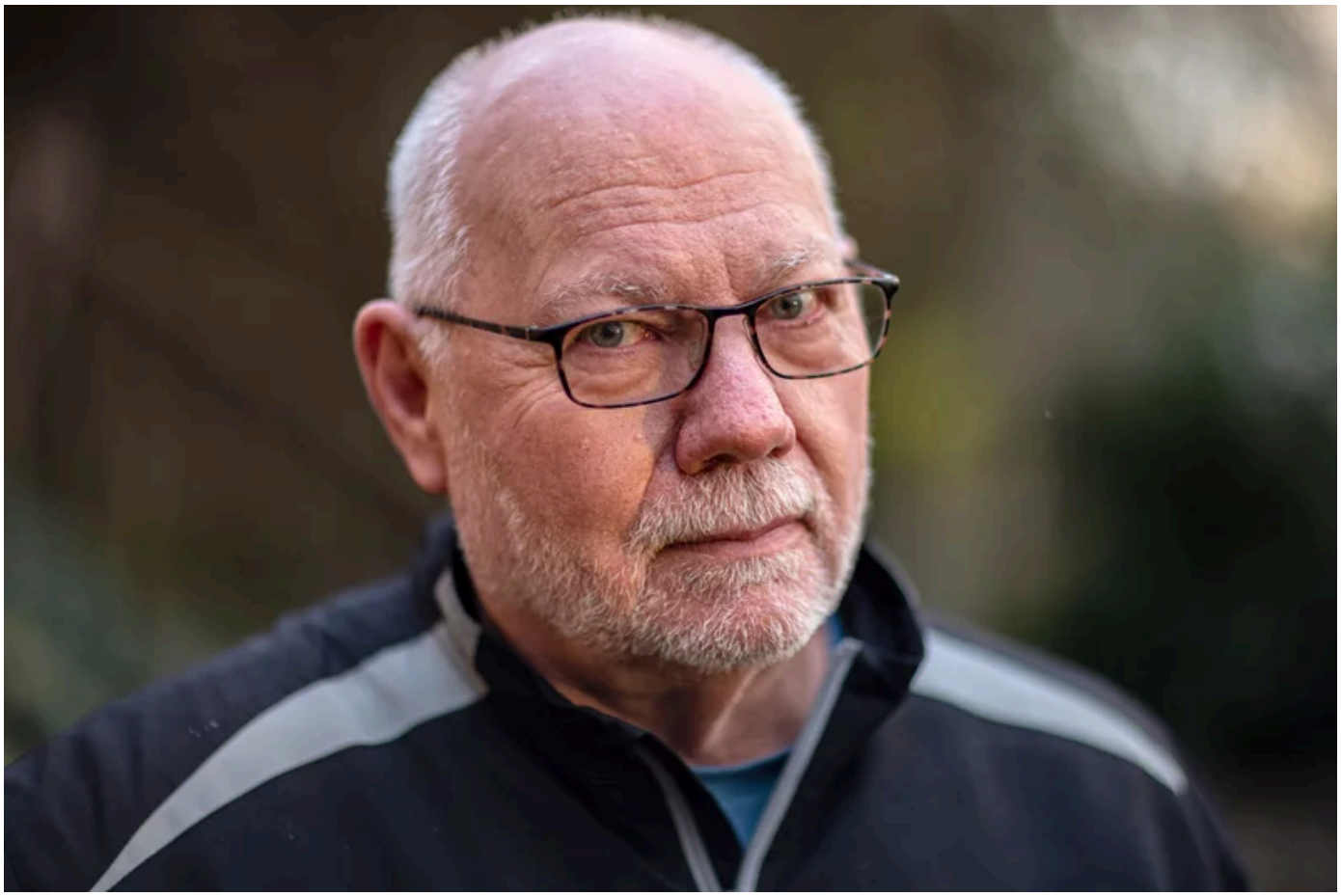
Reproductive health experts have said relaxing that requirement could help ease the growing burden on abortion clinics in states where abortion is legal. And perhaps nowhere is the potential for that greater than in Washington state, where efforts are underway to open up access to medication abortion in a radical new way: by training pharmacists not only to dispense abortion pills but also to prescribe them to their walk-in patients.

"We think this could have a huge impact in our state," says Don Downing, a professor emeritus of clinical pharmacy at the University of Washington in Seattle. Medication abortion now accounts for more than half of abortions in the U.S.

Last spring, Downing and colleagues launched the Pharmacy Abortion Access Project to provide community pharmacists in Washington with training on screening for medication abortion eligibility, prescribing abortion pills, and dispensing them from their brick-and-mortar stores — a streamlined model of care that currently exists nowhere else in the United States.

"This is about meeting women where they are," says Downing, adding that close to 90% of Americans live within 5 miles of a community pharmacy and that patients visit their pharmacist almost twice as frequently as they visit their primary care physician. "We do believe this can serve as a model for other states."

And it may be more than a matter of physical access. Pharmacists are consistently rated among the most trusted health care providers, he says. "So we think there may be people — possibly many people — for whom it's too frightening, too stigmatizing to go to a doctor but who, as we've seen over the years, are very comfortable coming to us."



Last spring, pharmacist Don Downing and colleagues launched the Pharmacy Abortion Access Project to provide community pharmacists in Washington with training for prescribing medication abortion.

Mike Kane for NPR

There are 10 pharmacists in the first cohort, and Downing expects them to start prescribing in the next few weeks. But word is spreading, he says. More and more calls are coming in. And Downing frequently finds himself explaining how a law passed more than 40 years ago first opened the way for this model, by making it possible for pharmacists in Washington to prescribe any FDA-approved drug.

Redefining the pharmacy

In 1979, Washington became the first state in the nation to enact legislation allowing for the formation of collaborative practice agreements, or CPAs. Under the agreements, a licensed prescriber such as a physician or a nurse practitioner can delegate to a pharmacist the authority to prescribe a given drug and administer it to patients.

This step opened the way for pharmacists to expand their scope of practice in Washington — and Downing has spent his career working to expand it further.

As a doctoral student in the mid-1970s, Downing was part of a growing push led by the Indian Health Service to use pharmacists to reach underserved communities. Concerned about the low immunization rates among Native Americans long neglected by the federal government, he helped Native activists in Seattle build the country's first urban tribal clinic. After graduating, he went to work with other tribes, serving as a pharmacist medical provider on reservations throughout the region.

Those experiences opened Downing's eyes to the vast inequities in access to basic health services — and the untapped potential for pharmacists to help close that gap. In the early 1990s, he and colleague Jackie Gardner, a professor of epidemiology at UW, began training community pharmacists to administer flu shots and other vaccines, leading to the launch of the first formalized training program in 1994. Today, pharmacists in all 50 states routinely administer vaccines.

Following that success, Downing, Gardner and other colleagues at UW partnered with the nonprofit PATH to develop the nation's first pharmacist-provided emergency contraception program. At the time, women who needed emergency contraception had to schedule a doctor's appointment, which often meant taking time off from work or school, finding transportation and arranging for child care. "We knew there was unmet demand," says Downing. "But we had no idea how much."

When the pilot project started in 1998, they had hoped to reach about 1,500 women, he says, "and we thought we were being optimistic." By the end of the following year, they'd enrolled close to 12,000, with pharmacists in Washington writing more prescriptions for emergency contraception in a single month than the state's doctors had written in the previous year.

Emergency contraception is now over-the-counter, but having pharmacists prescribe it was an important step, says Elisa Wells, a co-founder of the abortion rights group Plan C, who helped start the project while working at PATH. "And for something like emergency contraception, where there's a clock ticking — and this is true for abortion as well — that convenience is crucial."

Downing also worked for years to get pharmacists reimbursed for these clinical services by insurers. Finally, in 2015, Washington's Gov. Jay Inslee signed a law making Washington the first state in the nation to formally recognize pharmacists as medical providers and require that they not be excluded from health insurance provider networks.

"That allowed pharmacists in Washington to function at the full extent of their licensure and training," said Jenny Arnold, chief executive officer of the Washington State Pharmacy Association, noting that pharmacists today typically complete a doctorate degree and many go on to do residencies. "There's a lot more they can do than just make sure the patient gets the right meds in the bottle."

And yet in many states, she says, pharmacists are still greatly underutilized. While all states now allow pharmacists to enter into a collaborative practice agreement, most limit pharmacists' prescriptive authority to certain patients, circumstances or types of drugs. Washington's law governing CPAs is one of the broadest and most flexible, allowing the clinicians themselves to decide what to prescribe and to whom.

In Washington, nearly every pharmacist is signed onto a CPA, says Arnold. In addition to prescribing contraceptives and giving flu shots, many pharmacists have long played a lead role in managing chronic conditions — everything from heart disease and hypertension to diabetes, depression and pain. "Pharmacists are very integrated into their communities," she says. "They're open on evenings, weekends and holidays, and oftentimes you don't need an appointment to see one."

Obstacles to providing medication abortion

That doesn't mean every pharmacist in Washington is going to start prescribing abortion pills, Arnold says.

For one, many say they lack sufficient knowledge of medication abortion, which is not covered by pharmacy school curricula. That's where Downing's training program fills a gap, guiding pharmacists through a "no-test" protocol designed for evaluating patients remotely, without the need for ultrasound, pelvic exam or bloodwork. The protocol includes guidelines for appropriate patient selection, treatment regimen and follow-up care, and it excludes patients with symptoms of, or risk factors for, ectopic pregnancy.

The largest U.S. study of no-test screening for medication abortion to date found it to be safe and effective, with outcomes similar to those for patients who received in-person care.

There are several administrative hurdles, too — both for the pharmacist and the pharmacy that employs them.

While the FDA now allows retail pharmacies to dispense mifepristone, it also requires those pharmacies to undergo a new certification process. Currently, just one pharmacy in Washington is known to have been certified. Major pharmacy chains CVS and Walgreens announced on March 1 that they have been certified to start dispensing mifepristone. A spokesperson for Walgreens told NPR that the company will begin dispensing it in a phased rollout at locations in New York, Pennsylvania, Massachusetts, California, and Illinois.

To become certified, a pharmacy must meet a number of regulations related to record-keeping, adverse-event reporting and more. Pharmacies must also appoint a representative to ensure mifepristone is distributed in compliance with the FDA's Risk Evaluation and Mitigation Strategies program, or REMS, the stringent set of rules by which the agency regulates certain drugs.

Among them is the requirement that doctors and other health care providers — including pharmacists — who wish to prescribe mifepristone first register with one of the two licensed manufacturers.

That requirement has long been a significant barrier for primary care physicians, particularly those who work for religiously affiliated health systems. Indeed, though they've been capable of prescribing mifepristone since its approval in 2000, just a small fraction of family physicians and other clinicians currently offer medication abortion.

In Washington state, most primary care is provided by Catholic-owned or federally funded clinics — and for both of these, "the REMS makes it very difficult for a provider to 'register' to prescribe," says Emily Godfrey, a professor of family medicine and of obstetrics and gynecology at UW and the principal investigator for Access, Delivered, a project that helps primary care providers integrate telehealth medication abortion into their clinical practice. "And of course, pharmacists at these institutions would face the same hurdles."

Viability in other states

Nevertheless, interest in pharmacist-led provision of medication abortion appears to be growing, and not only in Washington. A bill pending in the New York State Assembly would grant pharmacists the authority to provide abortion medications under a "standing order" or non-patient specific prescription — the same way pharmacists administer vaccines and dispense naloxone, the opioid overdose reversal drug.

And in California, researchers at the University of California, San Diego recently reported the results of a proof-of-concept pilot study in which a pair of pharmacists safely and effectively provided medication abortions under the study protocol.

"We want pharmacists to be able to practice in the current environment, but we also want to train them to be ready for what's coming five years from now," in terms of expanded scope of practice, says Sally Rafie, the founder of Birth Control Pharmacist and a co-author of the study. Last spring, Rafie and colleagues published the results of a survey study of more than 900 pharmacists and pharmacy students in California that found that 75% "would be willing to prescribe abortion medications to their pharmacy clients if allowed by law."

A limited number of pharmacists in California may already be legally allowed to prescribe mifepristone if they've gotten an advanced practice certification. Rafie says she's hopeful that in the future the state may establish a pathway for all pharmacists to prescribe the drug.

Don Downing, near his home just east of the University District in Seattle. Downing has worked his whole career to expand the role of pharmacists in Washington state.
Mike Kane for NPR

Legal challenges to mifepristone

Meanwhile, a serious legal challenge to the FDA's nearly 25-year-old approval of mifepristone continues to threaten access to the drug across the country.

The Supreme Court is considering whether the FDA may be required to roll back changes it had made in recent years to make the drug more accessible, including allowing it to be sent through the mail and prescribed by health care providers who are not physicians.

Until the Supreme Court issues a decision later this year, mifepristone remains available under the current rules.

"Medication abortion is extremely safe and extremely effective," said Ushma Upadhyay, a professor at the University of California, San Francisco School of Medicine and a chair of the Society of Family Planning's #WeCount project, an ongoing tally of abortions in the U.S.

In October, Upadhyay and colleagues reported that despite abortion bans in 14 states and new limits imposed in seven others, the past year saw a slight uptick in

abortions across the country, with major increases in states where abortion remains legal.

"All of the moves made to shore up access in the legal states — things like expanding insurance coverage of abortion, more protections for providers and building up the telehealth infrastructure — are having a real impact," she says. Pharmacist prescribing of mifepristone puts the drug a step closer to over-the-counter, she adds. "It's one stop. And to be able to get your medication the same day, to not have to wait for it to come in the mail — that is huge."

Patrick Adams is a freelance journalist based in Atlanta.

pharmacists pharmacies mifepristone medication abortion abortion drug

EXHIBIT 58

CVS and Walgreens to dispense the abortion pill mifepristone - NBC News

ABORTION RIGHTS

CVS and Walgreens to start dispensing the abortion pill mifepristone

The two pharmacy chains said they received certification to dispense mifepristone, following a rule change the Food and Drug Administration issued last year.

Medication abortion made up more than half of all U.S. abortions in 2020, according to the Guttmacher Institute.

Justin Merriman / Bloomberg via Getty Images

March 1, 2024, 2:36 PM CST

By Chloe Atkins

CVS and Walgreens announced on Friday that they will soon start dispensing mifepristone, one of the two drugs used for medication abortions, in states where abortion is allowed.

The two large pharmacy chains said they had received certification to dispense mifepristone, following a rule change the Food and Drug Administration finalized in January 2023.

App. 000971

The FDA decision broadened the availability of abortion pills by allowing pharmacies to dispense them to patients in person or or by mail, though neither CVS nor Walgreens are sending the medication by mail yet. Previously, patients were required to pick up the medication in person at a clinic, medical office or hospital.

Mifepristone is the first of two pills used in medication abortions. The second is misoprostol.

The FDA policy still requires pharmacies to meet certain requirements and complete a set of forms to get certified to sell mifepristone – that's the process CVS and Walgreens have completed.

Walgreens said it will begin dispensing mifepristone pills within a week – consistent with state laws – in select locations in California, Illinois, Massachusetts, New York and Pennsylvania.

“We are beginning a phased rollout in select locations to allow us to ensure quality, safety, and privacy for our patients, providers, and team members,” Walgreens said in a statement.

CVS said it is “working with manufacturers and suppliers to secure the medication and are not yet dispensing it” in any of their pharmacies.

The statement added that pharmacies will begin to fill prescriptions in Massachusetts and Rhode Island in the “weeks ahead,” then “will expand to additional states, where allowed by law, on a rolling basis.”

CVS and Walgreens said mifepristone will be only dispensed at their physical pharmacy locations, though Walgreens added that home delivery via a courier service will be available for customers at select locations in accordance with state and federal laws.

Pharmacies in states where abortion is banned will not sell mifepristone.

Medication abortion made up more than half of all U.S. abortions in 2020, according to the Guttmacher Institute, a research organization that advocates for abortion access.

Boxes of mifepristone. Allen G. Breed / AP file

Following the CVS and Walgreens announcements, President Joe Biden issued a statement praising the change.

“With major retail pharmacy chains newly certified to dispense medication abortion, many women will soon have the option to pick up their prescription at a local, certified pharmacy–just as they would for any other medication,” Biden said. “I encourage all pharmacies that want to pursue this option to seek certification.”

CVS and Walgreens’ announcements come as the Supreme Court is poised to hear oral arguments in March in a high-stakes case that takes aim at FDA policies that have expanded access to mifepristone in recent years. It will be the first significant abortion case before the Supreme Court since its decision in Dobbs v. Jackson Women's Health Organization overturned the constitutional right to abortion.

Chloe Atkins

Chloe Atkins reports for the NBC News Investigative Unit, based in New York. She frequently covers crime and courts, as well as the intersection of reproductive health, politics and policy.

EXHIBIT 59

Pharmacy Directory - GenBioPro

PUTTING ACCESS INTO PRACTICE

MEDICAL ABORTION ON YOUR TERMS

Pharmacy Directory

Here is a list of pharmacy locations that distribute mifepristone.

Not all certified pharmacies dispensing GenBioPro generic mifepristone have elected to be listed here. If you wish to use a pharmacy to dispense, please email info@genbiopro.com (mailto:info@genbiopro.com). We can help you find your nearest certified pharmacy.

National pharmacies

CVS Pharmacy (https://www.cvshealth.com/womens-health.html)
Pharmacy chain filling prescriptions in California, Colorado, Connecticut, DC, Delaware, Hawai'i, Illinois, Massachusetts, Maryland, Maine, Michigan, Minnesota, New Hampshire, New Jersey, Nevada, New Mexico, New York, Oregon, Pennsylvania, Rhode Island, Virginia, Vermont, and Washington.

Honeybee Health (https://honeybeehealth.com/)
Mail-order pharmacy filling prescriptions in multiple states.

Regional pharmacies

Arizona

Fairmont Pharmacy
(https://www.fairmontpharmacy.com/)
5068 N. Central Ave.
Phoenix, AZ

California

AllCare Pharmacy (https://allcarerx.net/)
331 Main St.
Salinas, CA

Auburn Pharmacy and Compounding
5643 Auburn St., Suite B
Bakersfield, CA

CureStat Rx (https://curestatrx.com/)
6725 Mesa Ridge Rd., Suite 230
San Diego, CA

Haller's Pharmacy and Medical Supply
(https://www.hallerspharmacy.com/)
37323 Fremont Blvd.
Fremont, CA

Komoto Pharmacy
(http://www.komotopharmacy.com)
1017 Ellington St.
Delano, CA

Ming and H Drugs (http://www.minghdrugs.com)
1717 Ming Ave.
Bakersfield, CA

Normandy Pharmacy
5112 Hollywood Blvd.
Los Angeles, CA

Normandy Pharmacy 2
12914 B. Sherman Way
North Hollywood, CA

Pucci's Pharmacy (https://www.puccirx.com/)
3257 Folsom Blvd.
Sacramento, CA

SMP Pharmacy Northridge
(https://smppharmacy.com/)
18546 Roscoe Blvd., #102
Northridge, CA

St. Mary's Pharmacy
(https://fresno.medicineshoppe.com/)
3150 E. Shields Ave., Suite 105
Fresno, CA

Sun Pharmacy
2559 S. King Rd., Suite B10
San Jose, CA

TLC Medical Arts Pharmacy
(https://www.tlcmedicalartspharmacy.com/)
1500 W. West Covina Pkwy., #100
West Covina, CA

USC Medical Plaza Pharmacy
(https://pharmacies.usc.edu/pharmacies/medical-plaza-pharmacy/)
1510 San Pablo St., Suite 144
Los Angeles, CA

Wellspring Pharmacy
(https://www.wellspringrx.com/)
4184 C Piedmont Ave.
Oakland, CA

Connecticut

St. Francis Rx #1
100 Woodland St.
Hartford, CT

St. Francis Rx #2
131 Coventry St.
Hartford, CT

Maryland

SMP Pharmacy Mid-Atlantic
(https://smppharmacy.com/)
9601 Blackwell Rd., #230
Rockville, MD

UMMC Pharmacy at Redwood
(https://www.umms.org/ummc/locations/redwood-pharmacy)
11 Paca St.
Balitmore, MD

Nevada

A1C Pharmacy (https://a1cpharmacy.com/)
4601 West Sahara Avenue, #P
Las Vegas, NV

Renown Pharmacy
(https://www.renown.org/Health-Services/Pharmacy)
21 Locust St.
Reno, NV

Renown Pharmacy
(https://www.renown.org/Health-Services/Pharmacy)
75 Pringle Way
Reno, NV

Renown Pharmacy
(https://www.renown.org/Health-Services/Pharmacy)
10101 Double R Blvd.
Reno, NV

New York

Beacon Pharmacy
(https://www.beaconpharmacyrx.com/)
103 Main St.
Port Washington, NY

Genesee Campus Apothecary
(http://www.rochesterhealth.com/healthcaredirectory/aprofile/A000000078/the-genesee-campus-apothecary)
89 Genesee St.
Rochester, NY

Glen Head Pharmacy
(https://www.glenheadrx.com/)
699 Glen Cove Ave.
Glen Head, NY

Globe Drug Store (https://globedrugstore.net/)
405 86th St.
Brooklyn, NY

Hunold Pharmacy
(https://www.hunoldpharmacy.com/)
94 Main St.
Port Washington, NY

Medford Chemists
(https://rx.medfordchemists.com/)
5608 Route 112
Medford, NY

Roslyn Pharmacy (https://www.roslynrx.com/)
1314 Old Northern Blvd.
Roslyn, NY

Sunway Pharmacy
5723 5th Ave.
Brooklyn, NY

Rhode Island

Lifespan Pharmacy (http://lifespan.org)
593 Eddy St., Davol Building
Providence, RI

South Carolina

Sweetgrass Pharmacy and Compounding
(https://www.sweetgrasspharmacy.com/)
3485 Park Avenue Blvd.
Mt. Pleasant, SC

Texas

Halowells
2522 Westminster St.
Pearland, TX

Washington

Jim's Pharmacy & Home Health
(https://jimsrx.com/)
424 E. Second St.
Port Angeles, WA

Ostrom's Drug & Gift (https://ostroms.com/)
6414 NE Bothell Way
Kenmore, WA

Wisconsin

Meriter Outpatient Pharmacy
(https://www.unitypoint.org/madison/outpatient-pharmacy.aspx)
202 S. Park St.
Madison, WI

IMPORTANT SAFETY INFORMATION

Mifepristone tablets, 200 mg is indicated, in a regimen with misoprostol, for the medical termination of intrauterine pregnancy through 70 days gestation.

IMPORTANT SAFETY INFORMATION

WARNING: SERIOUS AND SOMETIMES FATAL INFECTIONS OR BLEEDING

Serious and sometimes fatal infections and bleeding occur very rarely following spontaneous, surgical, and medical abortions, including following Mifepristone tablets, 200 mg use. No causal relationship between the use of Mifepristone tablets, 200 mg and misoprostol and these events has been established.

- **Atypical Presentation of Infection. Patients with serious bacterial infections (e.g., *Clostridium sordellii*) and sepsis can present without fever, bacteremia, or significant findings on pelvic examination following an abortion. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. A high index of suspicion is needed to rule out serious infection and sepsis.**
- **Bleeding. Prolonged heavy bleeding may be a sign of incomplete abortion or other complications and prompt medical or surgical intervention may be needed. Advise patients to seek immediate medical attention if they experience prolonged heavy vaginal bleeding.**

Because of the risks of serious complications described above, Mifepristone tablets, 200 mg is available only through a restricted program under a Risk Evaluation and Mitigation Strategy (REMS) called the mifepristone REMS Program.

Before prescribing mifepristone, inform the patient about the risk of these serious events. Ensure that the patient knows whom to call and what to do, including going to an Emergency Room if none of the provided contacts are reachable, if they experience sustained fever, severe abdominal pain, prolonged heavy bleeding, or syncope, or if they experience abdominal pain or discomfort, or general malaise (including weakness, nausea, vomiting, or diarrhea) for more than 24 hours after taking misoprostol.

Contraindications

- Administration of Mifepristone tablets, 200 mg and misoprostol for the termination of pregnancy (the "treatment procedure") is contraindicated in patients with any of the following conditions:
  - Confirmed or suspected ectopic pregnancy or undiagnosed adnexal mass (the treatment procedure will not be effective to terminate an ectopic pregnancy)
  - Chronic adrenal failure (risk of acute adrenal insufficiency)
  - Concurrent long-term corticosteroid therapy (risk of acute adrenal insufficiency)
  - History of allergy to mifepristone, misoprostol, or other prostaglandins (allergic reactions including anaphylaxis, angioedema, rash, hives, and itching have been reported)
  - Hemorrhagic disorders or concurrent anticoagulant therapy (risk of heavy bleeding)
  - Inherited porphyrias (risk of worsening or of precipitation of attacks)
- Use of Mifepristone tablets, 200 mg and misoprostol for termination of intrauterine pregnancy is contraindicated in patients with an intrauterine device ("IUD") in place (the IUD might interfere with pregnancy termination). If the IUD is removed, Mifepristone tablets, 200 mg may be used.

Warnings and Precautions

Infection and Sepsis

- As with other types of abortion, cases of serious bacterial infection, including very rare cases of fatal septic shock, have been reported following the use of Mifepristone tablets, 200 mg. Healthcare providers evaluating a patient who is undergoing a medical abortion should be alert to the possibility of this rare event. A sustained (> 4 hours) fever of 100.4°F or higher, severe abdominal pain, or pelvic tenderness in the days after a medical abortion may be an indication of infection.
- A high index of suspicion is needed to rule out sepsis (e.g., from *Clostridium sordellii*) if a patient reports abdominal pain or discomfort or general malaise (including weakness, nausea, vomiting, or diarrhea) more than 24 hours after taking misoprostol. Very rarely, deaths have been reported in patients who presented without fever, with or without abdominal pain, but with leukocytosis with a marked left shift, tachycardia, hemoconcentration, and general malaise. No causal relationship between Mifepristone tablets, 200 mg and misoprostol use and an increased risk of infection or death has been established. *Clostridium sordellii* infections have also been reported very rarely following childbirth (vaginal delivery and caesarian section), and in other gynecologic and non-gynecologic conditions.

Uterine Bleeding

- Uterine bleeding occurs in almost all patients during a medical abortion. Prolonged heavy bleeding (soaking through two thick, full-size sanitary pads per hour for two consecutive hours) may be a sign of incomplete abortion or other complications, and prompt medical or surgical intervention may be needed to prevent the development of hypovolemic shock. Counsel patients to seek immediate medical attention if they experience prolonged heavy vaginal bleeding following a medical abortion.
- Women should expect to experience vaginal bleeding or spotting for an average of 9 to 16 days. Women report experiencing heavy bleeding for a median direction of 2 days. Up to 8% of all subjects may experience some type of bleeding for 30 days or more. In general, the duration of bleeding and spotting increased as the duration of the pregnancy increased.
- Decreases in hemoglobin concentration, hematocrit, and red blood cell count may occur in patients who bleed heavily.
- Excessive uterine bleeding usually requires treatment by uterotonics, vasoconstrictor drugs, surgical uterine evacuation, administration of saline infusions, and/or blood transfusions. Based on data from several large clinical trials, vasoconstrictor drugs were used in 4.3% of all subjects, there was a decrease in hemoglobin of more than 2 g/dL in 5.5% of subjects, and blood transfusions were administered to ≤ 0.1% of subjects. Because heavy bleeding requiring surgical uterine evacuation occurs in about 1% of patients, special care should be given to patients with hemostatic disorders, hypocoagulability, or severe anemia.

Mifepristone REMS Program

Mifepristone tablets, 200 mg is available only through a restricted program under a REMS called the mifepristone REMS Program, because of the risks of serious complications.

Notable requirements of the mifepristone REMS Program include the following:

- Prescribers must be certified with the program by completing the Prescriber Agreement Form.
- Patients must sign a Patient Agreement Form.
- Mifepristone tablets, 200 mg must be dispensed to patients by or under the supervision of a certified prescriber, or by certified pharmacies on prescriptions issued by certified prescribers.

Further information is available at 1-855-MIFEINFO (1-855-643-3463).

Ectopic Pregnancy

Mifepristone tablets, 200 mg is contraindicated in patients with a confirmed or suspected ectopic pregnancy because mifepristone is not effective for terminating ectopic pregnancies. Healthcare providers should remain alert to the possibility that a patient who is undergoing a medical abortion could have an undiagnosed ectopic pregnancy because some of the expected symptoms experienced with a medical abortion (abdominal pain, uterine bleeding) may be similar to those of a ruptured ectopic pregnancy. The presence of an ectopic pregnancy may have been missed even if the patient underwent ultrasonography prior to being prescribed Mifepristone tablets, 200 mg.

Patients who became pregnant with an IUD in place should be assessed for ectopic pregnancy.

Rhesus Immunization

The use of Mifepristone tablets, 200 mg is assumed to require the same preventive measures as those taken prior to and during surgical abortion to prevent rhesus immunization.

Adverse Reactions

Most common adverse reactions (>15%) are nausea, weakness, fever/chills, vomiting, headache, diarrhea, and dizziness.

For additional information about mifepristone, see the Full Prescribing Information (https://www.genbiopro.com/mifepi), including Boxed Warning.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch (http://www.fda.gov/medwatch), or call 1-800-FDA-1088.

GenBioPro
PUTTING ACCESS INTO PRACTICE

COMPANY

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CONTACT US (HTTPS://GENBIOPRO.COM/CONTACT-US/)

STATEMENT REGARDING COMPLIANCE WITH CALIFORNIA HEALTH & SAFETY CODE § 119402 (HTTPS://GENBIOPRO.COM/CALIFORNIA-HEALTH-SAFE-CODE-119402/)

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EXHIBIT 60

'Shield' laws make it easier to send abortion pills to banned states - The Washington Post

Democracy Dies in Darkness

Health Brief

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'Shield' laws make it easier to send abortion pills to banned states

Analysis by Rachel Roubein
with research by McKenzie Beard

July 20, 2023 at 7:14 a.m. EDT

Happy Thursday! A big shout out to **Caroline Kitchener** for her excellent reporting in the top of today's newsletter.

And one note: I'll be heading out on summer vacay for a few days, and you'll have a great rotating cast of Post reporters bringing you this newsletter. See you next week! In the meantime, send all your news and tips to mckenzie.beard@washpost.com.

Today's edition: A hearing continues today on a lawsuit seeking clarity over exceptions to Texas's strict abortion ban. Sen. **Bernie Sanders** (I-Vt.) introduces a competing bill to fund community health centers as a critical deadline nears. **But first ...**

Aid Access launches new way to send abortion pills into states with bans

There's a new, more efficient pipeline sending abortion pills into states with bans.

Europe-based **Aid Access,** one of the largest abortion pill suppliers, revamped its protocols in mid-June. **The result?** Doctors in certain Democratic-led states with "shield" laws can now mail and prescribe pills directly to patients in antiabortion states.

The new process could ignite a complex interstate battle over abortion, where U.S. doctors in blue states are empowered to legally circumvent abortion laws in red states. The move could also undermine abortion bans at a time when antiabortion groups and doctors are seeking to revoke the approval of key medication used in over half of all abortions in the country.

Our colleague **Caroline Kitchener** dove deep into the new effort — and here's what she found.

The details

Previously, Aid Access only allowed Europe-based doctors to prescribe abortion pills to women in states where abortion is restricted. Those pills were shipped from India, and often took weeks to get to patients, which could push abortions well into the second trimester. (The **Food and Drug Administration** has approved mifepristone through 10 weeks gestation, though some studies have shown it can be used safely and effectively later in pregnancy.)

But new laws enacted over the past year are helping to streamline the process. Democratic-led states have moved to protect medical professionals and others who practice in states where abortion is legal from potential punishment in states with bans. **New York, Massachusetts, Washington, Vermont** and **Colorado** explicitly protect abortion providers who mail pills to restricted states from inside their borders, Caroline writes.

The new landscape: In less than a month, seven U.S.-based providers affiliated with Aid Access have mailed **3,500 doses** of abortion pills to people residing in states with bans. All together, the small group could help facilitate at least **42,000 abortions** in antiabortion states in a year. (Those numbers could grow, of course, if more providers join in.)

- As one expert told Caroline, the shield laws are "a huge breakthrough for people who need abortions in banned states," said **David Cohen,** a **Drexel University** law professor who focuses on abortion legislation. "Providers are protected in many ways as long as they remain in the state with the shield law."

Could doctors face legal risks?

That's a key question. And it could ultimately be resolved by the courts.

Some lawyers say the doctors — who are preparing and packaging the pills sent to restricted states themselves — could face repercussions, even if they don't travel to states that prosecute abortion providers. Some wonder whether states with abortion bans would try to extradite medical providers from states with shield laws, though that could prove difficult.

Jonathan Mitchell, the former solicitor general of Texas and architect of the state's roughly six-week ban, said it seems too early to predict what will happen, but that "there absolutely is a world in which they could get in trouble for it." (In many states with bans, those found guilty of distributing abortion pills could be sentenced up to at least several years in prison.)

But some involved in the effort say they're not worried.

"Everything I'm doing is completely legal," a doctor in New York's Hudson Valley, who spoke on the condition of anonymity to protect her safety, told Caroline. "Texas might say I'm breaking their laws, but I don't live in Texas."

Read the full story here.

Reproductive wars

Testimony begins in hearing seeking clarity on Texas's abortion exceptions

Three women gave accounts yesterday of being denied abortions or given delayed medical care due to confusion over the exceptions in Texas's strict abortion laws.

The testimony in a Texas courtroom was often emotional. At one point, one woman was reading a letter from her doctor describing how her baby had been diagnosed with a condition incompatible with life. She became sick on the stand, and the judge quickly recessed.

The case, which was filed by the Center for Reproductive Rights, is believed to be the first lawsuit from women denied abortions since the nation's highest court overturned *Roe v. Wade* last summer. The hearing began yesterday, as three women and a doctor took the witness stand for the plaintiffs, and will continue today.

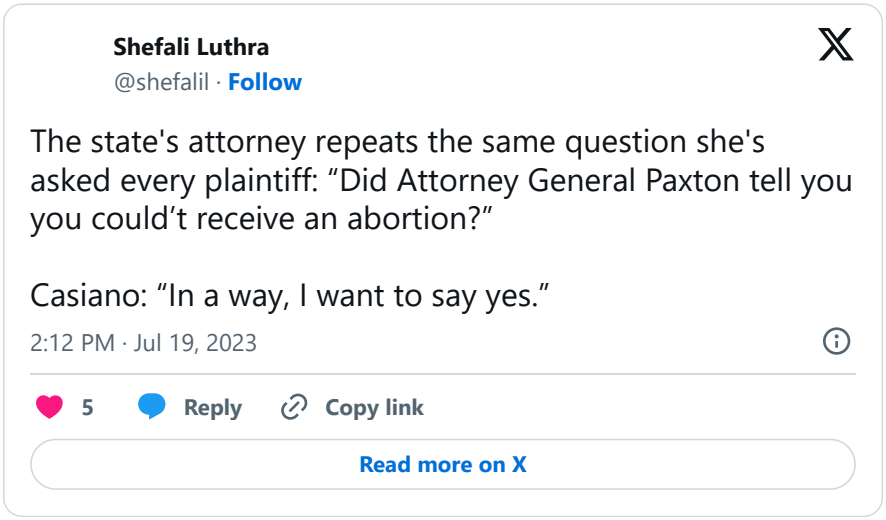
The legal challenge isn't seeking to overturn the state's abortion ban, but rather to clarify when an abortion is allowed in the case of a medical emergency. The plaintiffs are also seeking a temporary injunction blocking the state's ban in instances where a patient experiences a pregnancy complication.

During the hearing, **Molly Duane** — an attorney with the **Center for Reproductive Rights** — argued that the exceptions in the state's abortion ban are either "conflicting or lack definitions," and that doctors fear the high penalties they'd face if they're found to violate the law.

On the other side, **Amy Pletscher,** who represented the Republican attorney general's office, called the legal challenge an "ideological crusade."

"Plaintiffs simply do not like Texas's restrictions on abortion," she said.

Shefali Luthra, reporter at the 19th:



On the Hill

Sanders introduces bill to fund community health centers

Senate HELP Committee Chair Bernie Sanders (I-Vt.) unveiled a bill yesterday that aims to overhaul the country's primary health-care system — a move that indicates there isn't a bipartisan compromise in the Senate over funding for health centers that provide care to the country's most vulnerable.

The details: The legislation would invest **$20 billion** per year over a five-year period to expand community health centers and expand the health workforce. **The panel is slated to mark up the legislation next Wednesday.**

Sanders's proposal comes days after the panel's top Republican, Sen. **Bill Cassidy** (La.), introduced a bill to reauthorize the fund comprising roughly **70 percent** of federal dollars for health centers, which is set to expire Sept. 30. That legislation mirrors the funding plan the **House Energy and Commerce Committee** advanced with unanimous support in late May.

The view from Cassidy: "This is partisan legislation that cannot pass the Senate," he said in a statement. "There is already reauthorization legislation that unanimously passed out of the House E&C committee, has been introduced in the Senate and is endorsed by community health centers. **That is the bill we should mark up next week**."

Meanwhile, in the House …

The **House Energy and Commerce Committee** advanced two Republican-drafted bills aimed at reauthorizing an emergency preparedness law. The votes were **28-23** and **27-22.**

In a political maneuver ahead of the hearing, the panel's Democrats introduced their own version of the emergency preparedness bill that included a slate of measures they had been pushing to address the country's drug shortages.

One more thing: The panel also voted unanimously to advance a bipartisan bill that would reauthorize an array of addiction treatment and recovery programs first enacted as part of the **Support Act**, which Congress passed in 2018.

Frank Pallone Jr. (N.J.), the panel's top Democrat:

> Today @EnergyCommerce Committee is marking up 15 health care bills including a bipartisan bill to help those struggling with opioids. Unfortunately, we're also voting on a partisan Republican bill that will leave our nation unprepared to face the next public health emergency. pic.twitter.com/IOXdsvvTMy
> — Rep. Frank Pallone (@FrankPallone) July 19, 2023

Rep. Jeff Duncan (R-S.C.), a member of the committee:

> My amendment to H.R. 4420, the Preparedness and Response Authorization Act, that saves American taxpayers $65 million, just passed in the @HouseCommerce Committee. This amendment strikes funding increases to the very public health agencies that failed us during COVID, as they… pic.twitter.com/Awe2CafvAM
> — Rep. Jeff Duncan (@RepJeffDuncan) July 19, 2023

Across the Capitol …

Senate Majority Leader **Chuck Schumer** (D-N.Y.) will allow a vote to repeal the **Pentagon**'s abortion policy, in an effort to sway Republican Sen. **Tommy Tuberville** (Ala.) to lift his hold on scores of military promotions, **Politico**'s **Burgess Everett** reports.

- **If he "wants to have an affirmative vote, we would not object to it," Schumer said yesterday.** "Tuberville said he wanted a vote, we'll see what happens."

What we're watching: Schumer's offer could come as an amendment vote on the must-pass **National Defense Authorization Act** or as a stand-alone vote, although both would likely fail in the Democratic-controlled chamber. Privately, some Republicans have expressed worries that such an outcome wouldn't be enough to satisfy Tuberville.

Coronavirus

Health officials: Funding cuts to Chinese lab separate from congressional probes

The federal health department suspended funding this week to the **Wuhan Institute of Virology**, the Chinese lab at the center of investigations about the coronavirus's origins.

Current and former health officials told our colleague **Dan Diamond** that the decision was independent from congressional investigations into the virus's origin, and that it doesn't indicate confirmation of theories that the virus leaked from the facility. Instead, the order was "necessary to mitigate any potential public health risk," after the research institute failed to turn over key documents about its work on coronaviruses, according to a **Department of Health and Human Services** memo.

Read the full story here.

Rep. Brad Wenstrup (R-Ohio), who chairs the House panel investigating the coronavirus response:

Daybook

On tap today: Our colleague **Sabrina Malhi** will host a live Q&A with **Peter Hotez**, a prominent scientist and pediatrician, on misinformation surrounding vaccines. The event will take place at 1 p.m. Submit your questions here.

Health reads

Revolving Door: DEA's No.2 quits amid reports of previous consulting work for Big Pharma (By Joshua Goodman and Jim Mustian | The Associated Press)

Florida kept disabled kids in institutions. A judge is sending them home. (By Amanda Morris | The Washington Post)

Gene variant may be why some test positive for virus with no covid symptoms (By Aara'L Yarber | The Washington Post)

Sugar rush

Thanks for reading! See y'all tomorrow.

EXHIBIT 61

How blue states are responding to the post-Roe world - The Washington Post

Democracy Dies in Darkness

Health Brief

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How blue states are responding to the post-Roe world

Analysis by Rachel Roubein
with research by McKenzie Beard

June 21, 2023 at 8:11 a.m. EDT

Happy official first day of summer (the absolute best season) Send news and tips for the longest day of the year to rachel.roubein@washpost.com. Not a subscriber? Sign up here.

Today's edition: Half of OBGYNS in states with bans say they've had patients who were unable to obtain an abortion despite seeking one, a new survey finds. A federal judge strikes down Arkansas's first-in-the-nation ban on gender transition care for minors. **But first ...**

Democratic-led states are passing shield laws, solidifying abortion rights post-Roe

Democratic-led states rushed to shore up abortion protections in the first legislative season of the post-*Roe* era.

Lawmakers in blue states passed an array of bills, from solidifying abortion rights to expanding access to medication abortion to shielding providers who practice in states where abortion is legal.

The goal? Democrats are seeking to ensure abortion remains legal in their states, while continuing to serve as a destination for women who live in conservative areas with strict abortion bans. Their efforts this year built on legislation passed in 2022 in anticipation of the Supreme Court overturning *Roe v. Wade* — and some abortion rights advocates say it's just the beginning.

- "This is truly the next iteration of innovation and creativity at the state level, as well as at the local level," said **Andrea Miller,** the president of the **National Institute for Reproductive Health.**

We've written a lot about how abortion bans fared during state legislative sessions this year. This morning, we're turning to trends in states seeking to counteract such restrictions.

Trend #1: Some states sought to shore up abortion rights.

There were several prominent examples of this effort popular among liberal states and abortion rights groups.

In Minnesota: In a surprising upset during November's midterm elections, Democrats took full control of the state government for the first time since 2014. They rushed to enact a law codifying the right to an abortion into state law. (The procedure was already protected under a 1995 state Supreme Court decision, but supporters said they wanted to take the decision out of the hands of "individual judges.")

In Michigan: Democrats also won control of both the state House and Senate for the first time in nearly four decades. In April, Gov. **Gretchen Whitmer** (D) signed legislation to repeal a 1931 near-total abortion ban, which came after voters in the state approved a constitutional amendment to enshrine the right to an abortion into the state constitution.

In Maryland: The General Assembly gave the greenlight to let voters decide whether to enshrine abortion rights into the state constitution next year.

In New York: For the second time, state lawmakers passed an amendment to enshrine abortion rights into the state constitution. That means the measure will also now head to voters next year.

More from Whitmer:

Today, we are repealing Michigan's extreme 1931 law that bans abortion and criminalized nurses and doctors for doing their jobs.

This is long overdue. 🧵 pic.twitter.com/PCOqJhTtb4
— Governor Gretchen Whitmer (@GovWhitmer) April 5, 2023

Trend #2: Democrats look to shield providers.

While the specifics in states may differ, this policy is generally aimed at protecting medical professionals and others who practice in states where abortion is legal from punishment in states with bans.

Advocates for such laws acknowledge there don't appear to be cases of charges filed against providers in such instances. But they say the new measures send a message and act as a guard against lawsuits.

In New York: The legislature gave approval yesterday to legislation granting legal protection for doctors in the state to prescribe and send abortion pills to patients in states with bans. Gov. **Kathy Hochul** (D) has indicated her support for the idea of a new shield law, per **the New York Times.**

The state certainly isn't the only one to enact new shield laws. In Vermont, Republican Gov. **Phil Scott** signed a shield law that explicitly protects access to mifepristone, even if the federal government withdraws approval of the commonly used abortion pill.

Other states passing various forms of shield laws include **Hawaii, Illinois, Minnesota, Colorado** and **several more.**

David S. Cohen, a professor at Drexel University's law school:

BIG NEWS out of New York. It becomes the fifth state to pass this type of shield law, but the first with providers who are openly talking about how they are going to mail pills to ban states. 1/2 https://t.co/g75rKXqbJS
— David S. Cohen (@dsc250) June 20, 2023

Trend #3: States are testing out a smattering of new bills.

States tend to follow each other's lead, so it's worth watching closely what could emerge as a trend during the next legislative cycle.

Some bills that caught our eye:

- In **New York,** Hochul signed a bill aimed at ensuring all public colleges and universities offer medication abortion.
- In **Washington state,** a new law will ensure the Department of Corrections can sell, deliver, distribute and dispense abortion pills.
- And **Rhode Island** has become the latest state with a measure letting state funds cover abortion in the Medicaid program and for those on state employee insurance plans.

Meanwhile ... State and local governments are putting more money toward expanding access to abortion. Since the Supreme Court's decision, at least 15 municipal governments and six states have put **nearly $208 million** toward funding abortion, reproductive health services, patient navigation programs and other services, according to the **National Institute for Reproductive Health.**

Rhode Island Gov. Dan McKee (D):

> Here in Rhode Island, we will always protect a woman's right to choose and ensure equal access to these crucial health care services.
>
> I'm proud to sign the Equality in Abortion Coverage Act into law and include related funding in my budget proposal. pic.twitter.com/wJvHG6p5Q0
> — Governor Dan McKee (@GovDanMcKee) May 18, 2023

Chart check

New this a.m.: How OBGYNs say new abortion restrictions are affecting maternal care

In the year since the Supreme Court overturned *Roe v. Wade*, half of OBGYNs working in states with abortion bans say they have had patients who were unable to terminate their pregnancies despite seeking to do so, according to a new survey out this morning from **KFF**.

By the numbers: Across the country, **68 percent** of OBGYNs said the effects of the *Dobbs* ruling have made managing pregnancy-related medical emergencies worse, while **64 percent** said they believe the ruling has exacerbated pregnancy-related mortality, according to the poll.

Zooming out: The findings represent the first nationally representative survey of OBGYNs since the ruling and provide one of the clearest views yet of how the decision has affected reproductive and sexual health care in the United States, The Post's **Kim Bellware** writes.

Transition care

Federal judge in Ark. blocks first ban on gender transition care

A federal judge struck down a 2021 Arkansas law prohibiting gender-affirming care for youth as unconstitutional yesterday, finding that the first-in-the-nation ban violated the rights of doctors and discriminated against transgender people, our colleague **Anne Branigin** reports.

U.S. District Judge **James Moody** of the Eastern District of Arkansas issued a permanent injunction forbidding the enforcement of the ban, which he had previously temporarily blocked from taking effect. The state plans to appeal the decision, Arkansas Attorney General **Tim Griffin** (R) said in a statement yesterday.

The bigger picture: Moody's closely watched ruling marks the first time a federal court has decided the legality of such restrictions, which have been adopted by at least 20 additional states in recent years, according to data compiled by the **ACLU**.

Arkansas Gov. Sarah Huckabee Sanders (R):

This is not "care" — it's activists pushing a political agenda at the expense of our kids and subjecting them to permanent and harmful procedures.

Only in the far-Left's woke vision of America is it not appropriate to protect children.

We will fight this and the Attorney… https://t.co/7wCeR4I1Vo
— Sarah Huckabee Sanders (@SarahHuckabee) June 20, 2023

The ACLU of Arkansas:

VICTORY! A federal district court judge has ruled against the Arkansas law banning gender-affirming care for trans youth, marking a groundbreaking victory to #ProtectTransYouth. We stand with all brave Arkansans fighting for their right to thrive & be healthy.🏳️‍⚧️ #arpx #arleg pic.twitter.com/TQrDoq3DED
— ACLU of Arkansas (@ArkansasACLU) June 20, 2023

Meanwhile …

The U.K.'s publicly funded **National Health Service for England** announced this month that it would limit the use of most puberty blockers for youth to clinical trials, saying more evidence is needed about their potential benefits and harms, the Wall Street Journal's **Jathon Sapsford** and **Stephanie Armour** reported over the weekend.

It's an argument that has cropped up among Republicans in Congress, with GOP lawmakers seizing on European doubts last week to support their push for increased caution and restrictions.

On the other side, Democrats contend Republicans are attempting to score political points. The U.S. medical community largely hasn't wavered in its support for clinical interventions. Last week, delegates from the **American Medical Association** endorsed a resolution reiterating support for access to gender-affirming care, saying that GOP claims "do not reflect the research landscape."

State scan

Inside how Gov. DeSantis used secretive panel to flip Florida Supreme Court

Our colleagues **Beth Reinhard** and **Josh Dawsey** published a deep dive yesterday on how Florida Gov. **Ron DeSantis** (R) seized on the unusual retirement of three liberal justices on the state Supreme Court at once to quickly reshape the panel into a conservative stronghold.

The details: After DeSantis narrowly won election in 2018, he enlisted the help of a secretive panel led by **Leonard Leo** — the key architect of the U.S. Supreme Court's conservative majority — to quietly vet judicial nominees to fill the vacancies.

The group grilled finalists on whether their principals matched those of the Federalist Society, an organization for conservative and libertarian attorneys that's led by Leo, people familiar with the process told The Post. DeSantis would go on to appoint three new justices in his first two weeks in office, flipping the court from what he described as a **4-3** liberal majority to a **6-1** conservative advantage.

Why it matters: The governor's efforts have yielded one of the most conservative state Supreme Courts in the country, and it is set to weigh the constitutionality of Florida's 15-week abortion ban in the coming months. A six-week ban that DeSantis approved this year also hangs in the balance, Beth and Josh write.

Our colleague Caroline Kitchener, who covers abortion for The Post:

> Soon, the FL supreme court is expected to issue a decision that will end most abortions in the third most populous state.
>
> DeSantis reshaped the court for this exact moment.
>
> Crucial reporting on how he did it, from @bethreinhard + @jdawsey1 https://t.co/C29Ix3oDvd
> — Caroline Kitchener (@CAKitchener) June 20, 2023

In other news from the states ...

In Kansas: State officials have agreed to not yet enforce a new law requiring clinics to inform patients of the disputed notion that a medication abortion can be interrupted using an unproven drug regimen until a judge weighs in on a formal request to block it, the **Topeka Capital-Journal**'s **Andrew Bahl** reports.

In Missouri: A judge rejected Republican Attorney General **Andrew Bailey**'s bid to stop a constitutional amendment to restore abortion rights, ordering him to approve Republican Auditor **Scott Fitzpatrick**'s cost estimate of the proposal within 24 hours of the ruling, **Kurt Erickson** reports for the **St. Louis Post-Dispatch**.

In other health news

- **The Senate voted 51-43 yesterday to confirm Julie Rikelman** to the U.S. Court of Appeals for the 1st Circuit, overcoming opposition from some Republicans and antiabortion advocates over her work as an abortion rights attorney.
- **The Supreme Court threw out a lower-court ruling yesterday** stopping South Carolina from cutting off public funding to Planned Parenthood, remanding the case to the U.S. Court of Appeals for the 4th Circuit for further consideration.
- **On the move: Anne Esposito**, **PhRMA**'s senior vice president for federal advocacy, will leave the lobbying group later this summer after over three years at the organization, **Stat**'s **Rachel Cohrs** reports.
- **The U.S. Preventive Services Task Force finalized its recommendation yesterday** urging primary care providers for the first time to screen all adults younger than 65 for anxiety disorders, The Post's **Lindsey Bever** reports.

Health reads

White House meets with drug firms on cost of overdose-reversal drugs (By David Ovalle l The Washington Post)

'It's beyond unethical': Opaque conflicts of interest permeate prescription drug benefits (By Bob Herman | Stat)

Impeached Texas Attorney General Partnered With Troubled Businessman to Push Opioid Program (By Kiah Collier | ProPublica)

Aird projected to oust Morrissey in Virginia Senate primary (By Laura Vozzella | The Washington Post)

Sugar rush

EXHIBIT 62

Group using 'shield laws' to provide abortion care in states that ban it
Abortion - The Guardian

Abortion

This article is more than **1 year old**

Group using 'shield laws' to provide abortion care in states that ban it

Aid Access ships medication abortion to all 50 states under the protection provided to clinicians serving patients in banned states

Boxes of mifepristone. Each of the Aid Access providers is sending approximately 50 packages a day. Photograph: Evelyn Hockstein/Reuters

Rebecca Grant

Sun 23 Jul 2023 07.00 EDT

Dr Linda Prine is providing abortion access to people in all 50 states, even those that have banned it. That might seem like an admission to be discreet about in post-Roe America, but Prine and her colleagues at Aid Access, a telemedicine abortion service, are doing it openly and in a way they believe is on firm legal ground.

On 14 July, Aid Access announced that over the past month, a team of seven doctors, midwives and nurse practitioners have mailed medication abortion to 3,500 people under the protection of "shield laws", which protect clinicians who serve patients in states where providing abortion is illegal. As soon as she learned about shield laws, Prine knew it represented an opportunity to go on the offensive, for those bold enough to try it.

"It made me think, OK, we need to fight back," Prine said. "We can't just take this lying down. We've got to do something. And this was what we can do."

From its origins, Aid Access has always been willing to test legal boundaries. It was started in 2018 by the Dutch physician Dr Rebecca Gomperts. At the time, FDA regulations prevented licensed US providers from mailing mifepristone, one of the two drugs in the medication abortion regimen, so Aid Access was structured like Gomperts' other telemedicine service, Women on Web. That process involved abortion seekers filling out an online consultation, and if eligible, Gomperts wrote a prescription from Europe and the pills were dispatched by a pharmaceutical partner in India.

Then, in 2020, Covid hit. And a federal judge suspended the FDA's in-person dispensing requirement for mifepristone. For the first time, legally prescribed medication abortion could be put in the mail. Aid Access used this opportunity to implement a hybrid model: in states where telemedicine abortion was legal, US clinicians handled the prescriptions, while in states where it wasn't, the pills continued to be mailed from India.

One drawback of shipping from India was the packages could take weeks to arrive. In addition to the stress and uncertainty involved in waiting, the time lag could push people past the 12-week limit recommended by the World Health Organization (although there is some emerging research that abortion pills can safely be taken later.) Covid also created concerns about shipping delays, and there was always the chance that customs could seize the packages.

> *The experience of wanting an abortion and then needing to wait three or four weeks to get it to happen ... that's just so hard*
> Dr Linda Prine

"The whole experience of wanting an abortion and then needing to wait three or four weeks to get it to happen, and not even be sure if those pills are ever going to come, that's just so hard," said Prine, who started working with Aid Access in 2021. "Who wants to do that? Nobody."

In March 2022, Prine read an op-ed by three legal scholars - David S Cohen of Drexel University, Rachel Rebouché of Temple University, and Greer Donley of the University of Pittsburgh - that introduced her to the idea of shield laws. The trio had published a paper titled The New Abortion Battleground in the Columbia Law Review, which outlined the ways that shield laws could protect abortion providers who treated patients in banned states if Roe fell.

"Certainly, it's not a surprise that post-Dobbs, there are going to be medical care providers who want to push the limits and care for as many people as they can, including people in other states," Cohen said in an interview. "People are going to do this, so we were thinking about what can the states where they live do to help them the most?"

Inspired by their work, a wave of states started passing shield laws. The first, in Connecticut, passed in May 2022. Massachusetts, the fifth state to pass a shield law in July 2022, was the first to include a telemedicine provision, meaning the state pledged to protect a provider licensed there who prescribed and mailed medication abortion pills, via telemedicine, to a patient in a state where abortion was banned - like Texas or Alabama. Currently, 15 states have shield laws in place, and five - Massachusetts, Washington, Vermont, Colorado and New York - have specific telemedicine protections.

> *Post-Dobbs, there are going to be medical providers who want to push the limits and care for as many people as they can*
> David S Cohen

Before Aid Access, no US providers had publicly tested them. Then, on 18 June, the organization started serving patients nationwide with providers licensed in those five states. Up to 13 weeks, they offer prescriptions for $150 with a sliding scale that asks people to pay whatever they can afford, with a shipping time of two-five days. (In a physical clinic, the median cost of medication abortion is over $500.)

"Now Aid Access is completely US provider-led," Lauren Jacobson, a nurse practitioner licensed in Massachusetts who joined Aid Access in February 2023, told the Guardian this month. "I think this is important because it sends the broader message that this is an American issue, a US problem, and taking advantage of the shield laws means we are returning this to an at-home solution."

In addition to enabling faster shipping times, Jacobson said some people also feel more secure knowing that the pills are coming from licensed clinicians through an FDA-approved pipeline. This is part of what distinguishes Aid Access from abortion pill suppliers that operate through unofficial channels, such as unregulated online pharmacies and clandestine community networks. While the non-profit Plan C has found those medications to be as advertised, and reliably safe and effective (and also, in the case of community networks, free), they don't offer interaction with a licensed clinician, and some people want that support as part of the process.

Right now, each of the Aid Access providers is sending approximately 50 packages a day. Prine said all the packing and postage and shipping tasks are a "big pain in the rear", but it's manageable. They are prepared to scale, both in terms of infrastructure and in terms of the legal challenges their actions could invite.

Cohen suggests there will be a "coming battle" as shield laws get tested, and emphasized that providers have the greatest amount of protection while they are in shield law states. Jacobson and Prine are not overly concerned about legal repercussions, but that doesn't mean they're not taking precautions.

If it happens, it happens, and we are prepared," Prine said. "But I'm definitely not taking any vacations in Texas."

Because shield laws are designed to protect providers, patient risk is a separate factor - one that's particularly acute for people from communities that face heightened surveillance from law enforcement. A state doesn't need to have an explicit law criminalizing people who have abortions to prosecute them, often under unrelated statutes, like the illegal concealment of human remains. Even before Dobbs, people were arrested for self-managing abortions. The risk is real, but in a moment where people have too few options and time is of the essence, Prine said, every option counts.

"I do consults all the time, and people are not saying, 'What about the legality of this?'" Prine said. "That is not their concern. Their question is, 'How soon will the pills arrive?' That is the number one question."

More on this story

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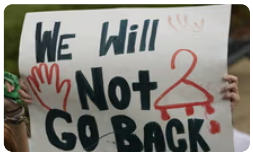

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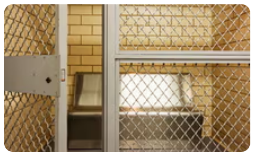

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EXHIBIT 63

How a network of abortion pill providers works together in the wake of new threats

ABORTION RIGHTS

How a network of abortion pill providers works together in the wake of new threats

Groups such as Aid Access, Hey Jane and Just the Pill stay in close contact to help women seeking abortions in states with bans.

A shield law provider packs abortion pills into envelopes to be sent from New York to states with bans.

Callan Griffiths / NBC News

April 7, 2024, 6:00 AM CDT

By Abigail Brooks and Dasha Burns

When the U.S. Supreme Court heard oral arguments in March about restricting access to the abortion drug mifepristone, Elisa Wells, co-founder and co-director of Plan C, was ready.

Plan C, an information resource that connects women to abortion pill providers, almost immediately saw a spike in searches for the medication.

With Florida's Supreme Court paving the way for the state's six-week abortion ban, Wells says she's expecting even more search activity and more creative thinking from providers.

"When these egregious decisions happen, first, they cause harm," she says. "And the second thing that happens is people get organized and mad and take action."

Since the Supreme Court overturned Roe v. Wade in its 2022 Dobbs decision, upending abortion access in the U.S., a network of abortion providers has sprung into action, weaving an abortion safety net across the country even as the procedure has been effectively banned in 15 states.

Providers such as Aid Access, Hey Jane and Just the Pill operate both within and outside the established health care system – including mailing abortion medications to women in states with bans, setting up mobile clinics and offering financial assistance – often staying in close contact with one another.

— Bottles of Misoprostol Tablets. NBC News

Many of those efforts center on access to abortion medication by mail, which the Food and Drug Administration made fully legal in 2021, creating a sort of "sisterhood of the traveling pill" that keeps groups connected as new restrictions on abortion arise.

Wells says Plan C called different providers for a meeting on how best to pivot in the changing abortion landscape.

"We had meetings where we introduced the providers to one another," she said. "All of these groups that normally would be competing with one another to come together and discuss, you know, how can we make a difference? How can we collectively address this issue?"

One such group is Aid Access, an online-only service based in the Netherlands. Originally a resource for women in the U.S. to get abortion pills from overseas, providers for the organization now ship pills from within the U.S. under telemedicine shield laws. The shield laws have been enacted in six states: California, Colorado, Massachusetts, New York, Vermont and Washington. The laws protect providers who prescribe and ship abortion pills to patients who live in states where abortion is banned or severely restricted.

"Before we had the shield law, we were mailing pills to the blue states, and only [pills from] overseas could be sent to the restricted states," said Dr. Linda Prine, a New York City-based shield law provider.

After New York's shield law passed, Prine said, "the first month we sent about 4,000 pills into restricted states, and now we're up to around 10,000 pills a month."

In a basement in upstate New York, another Aid Access provider who asked to not be identified for safety reasons underscored the importance of sending these pills from the U.S., rather than overseas.

"Sometimes they got stuck in customs," the provider explained as more than 100 prescriptions were being packaged around them, preparing to be shipped into states with bans.

"When you're doing a medication abortion, the faster you can get these medications, the better," the provider said in an interview. "It's easier, there's less bleeding, there's less cramping, and not to mention the anxiety that these women go through when they're waiting for those medications to get to them in the mail."

Boxes of pills will be packed into envelopes to ship around the country. Callan Griffiths / NBC News

Aid Access providers say they're sending pills to some who are in the most desperate situations – people who are willing to risk going outside the established health care system to access abortion services. The organization is exploring contingency plans in the event that access to the abortion pill through the mail is disrupted.

"We have so many patients who write to us who've been raped, who can't travel," the provider explained. "So we have to come up with other ways. I would say the last resort would be that these medications come again from overseas."

And while shield laws have yet to be challenged in courts, anti-abortion groups have taken notice.

"The fact remains that just because you are sitting in California does not mean that you are not violating the laws of Florida, Texas and 30 other states," Katie Daniel, state policy director for the anti-abortion group Susan B. Anthony Pro-Life America, told NBC News. "So I think they have a false sense of security about this."

In the six months after Dobbs, researchers saw an increase in women getting abortion medication outside the traditional health care system, with more than 27,000 additional instances, according to a recent study in the journal JAMA.

"These are groups like Las Libres, WeSaveUs, Arkansas Together," said Wells, who was a co-author of the study. "They're serving a significant number of people for an all volunteer-led effort."

Even within the traditional health care system, abortions via medication are increasing, too. Medication abortions accounted for 63% of all abortions in 2023, up 10% from the year before, according to research from reproductive rights think tank the Guttmacher Institute, making it the most common method for terminating a pregnancy.

— Envelopes filled with abortion pills. Callan Griffiths / NBC News

New York-based Hey Jane has seen that demand firsthand. Founder Kiki Freedman, an early Uber employee, launched the telemedicine-only abortion provider in 2018 after seeing other startups deliver medications and savings to customers via online-only prescription services. After the FDA eased restrictions on mifepristone prescriptions during pandemic, allowing women to get the abortion pill through the mail, Hey Jane took off. The company has shipped abortion pills to at least 50,000 patients, according to a statement.

“We have the added benefit of this sort of geographic fluidity where a doctor in New York can serve a patient in Illinois, or New Mexico if the doctor in New Mexico or the provider in New Mexico is busy,” said Freedman. “The other piece is financial accessibility and being able to access scalable ways of doing that, so via insurance, in particular.”

Hey Jane only prescribes and ships abortion medication to states where it’s legal, marking a difference from shield law providers and organizations like Aid Access.

Access to medication abortion helps patients avoid traveling and wait times at in-person clinics, and allows them to take the pills in private at home. While providers who ship to states with bans have struggled with traditional payment platforms, Hey Jane’s focus is on keeping access covered by insurance.

"Still, 75% of abortions are taking place in these 20 states we're in. It's still where the vast majority of care occurs," said Freedman. "It's not like access in those states has been seamless to date, right? It's always been difficult even there, and particularly post-Dobbs, wait times and things like that have really surged within those states."

Empty pill bottles in the basement of a shield law provider in New York will be filled with abortion medication.
Abigail Brooks / NBC News

Just the Pill provides abortion access to women in states with bans using discreet mobile clinics set up just across state lines.

The group has bulletproof vans in Colorado, Minnesota and Montana, and a brick-and-mortar location in Wyoming. Appointments are conducted via telemedicine, always within a state where abortion is legal, making shield laws unnecessary, a backstop a Just the Pill provider said is intentional, so care won't be interrupted if the shield laws are challenged.

"I totally support what these other organizations are doing," she said in an interview, asking not to be identified for safety reasons. "I'm cheering them on from afar, but want to make sure our service isn't challenged."

Just the Pill works with abortion funds, which provide financial assistance to patients who are seeking the procedure, to help patients travel across state lines for their appointments. After a telemedicine visit, pills are then prescribed and patients can pick them up and take them, all within the borders of a state where the procedure is

legal. Because just the Pill's clinics are mobile, they can travel along the borders of banned states and ensure they get as close as possible to women traveling from rural areas or long distances for care.

Meanwhile, Plan C is already working with more international pill providers to help with telehealth prescription access in the U.S. if telehealth visits for mifepristone are affected here, Wells said.

"We know we live in a time when anything can happen," Wells said. "We want to have as many alternate routes and access as possible. Many eggs and many baskets."

Abigail Brooks
Abigail Brooks is a producer for NBC News.

Dasha Burns
Dasha Burns is a correspondent for NBC News.

EXHIBIT 64

Inside a medical practice sending abortion pills to states where they're banned -- NPR

NATIONAL

Inside a medical practice sending abortion pills to states where they're banned

AUGUST 7, 2024 · 9:00 AM ET

Elissa Nadworny

“Welcome to modern abortion care,” says Angel Foster, who leads operations at what’s known as the MAP, a Massachusetts telehealth provider sending pills to people who live in states that ban or restrict abortion.

Elissa Nadworny/NPR

The packages, no bigger than a hardcover book, line the walls of the nondescript office near Boston. It's not an Etsy retailer or a Poshmark seller or, as the nearby post office workers believe, a thriving jewelry business.

These boxes contain abortion pills.

"Welcome to modern abortion care," says Angel Foster, as she holds up a box for mailing. Foster, who has an M.D. degree, leads operations at what's known as the MAP, a Massachusetts telehealth provider sending pills to people who live in states that ban or restrict abortion.

The MAP is one of just four organizations in the U.S. operating under recently enacted state shield laws, which circumvent traditional telemedicine laws requiring out-of-state health providers to be licensed in the states where patients are located. Eight states have enacted these shield laws.

Pregnant patients can fill out an online form, connect with a doctor via email or text and, if approved, receive the pills within a week, no matter which state they live in.

SHOTS - HEALTH NEWS

Abortion is becoming more common in primary care clinics as doctors challenge stigma

Shield law practices account for about 10% of abortions nationwide. There were 9,200 abortions a month provided under shield laws from January to March of this year, according to fresh data from the Society of Family Planning's WeCount project. And some researchers estimate that this number has risen since then and could be as high as 12,000 per month.

The rise of telehealth is part of why the number of abortions in the U.S. has continued to go up since the Supreme Court overturned *Roe v. Wade* in 2022 — even though 14 states have near-total abortion bans. In those states, shield law providers represent the only legal way people can access abortions within the established health care system.

"If you want to have your abortion care in your state and you live in Texas or Mississippi or Missouri, right now shield law provision is by far the most dominant way that you'd be able to get that care," says Foster.

Elissa Nadworny/NPR

Back in Massachusetts, Foster glances down at the list of today's patients. The practice's four OB-GYNs have signed off on prescriptions for nearly two dozen women — in Texas, Florida, Tennessee, Georgia, Alabama, Oklahoma and South Carolina. Most of today's patients are around six weeks along in their pregnancy. Many already have children.

"I really need an abortion pill. My state has banned it. My funds are really low," one patient wrote on the online form she filled out for the doctor.

"I'm a single mom with a kid under two," another wrote. "I can't afford a baby. I can't even afford this abortion."

Foster and her team serve patients who are up to 10 weeks pregnant and who are 16 or older. It costs $250 to get the two-drug regimen — mifepristone and misoprostol — in the mail, but there's a sliding scale and patients can pay as little as $5. The MAP is funded through abortion funds, individual donations and philanthropic gifts, and Foster has plans to apply for grants and state funding to help make the organization more sustainable. The MAP currently sends out about 500 prescriptions a month.

Yet to be tested in court, shield laws have some legal vulnerability

In the eight states with shield laws, abortion providers can treat out-of-state patients just as if they were in-state patients. The laws give abortion providers some protection from criminal prosecution, civil claims and extradition, among other threats. The laws have yet to be tested in court, but they certainly haven't gone unnoticed by lawmakers and groups looking to limit abortion.

"These websites are breaking the law … aiding and abetting crimes in Texas," says John Seago, the president of Texas Right to Life. "We want to use all the instruments that we have, all the tools available, to really fight against this new trend of abortion pills by mail."

Seago says providers should still be held responsible for committing a crime that is executed across state lines. "Mailing the abortion pill is a state jail felony according to our pro-life laws," he says, "but enforcement of those policies has been a real, real challenge."

Mifepristone, a drug used in abortion care, at the MAP's office in Massachusetts.
Elissa Nadworny/NPR

His organization has been looking for the right individual or circumstance to challenge shield laws directly in court. Three Republican-led states recently tried to sue the Food and Drug Administration over regulations allowing doctors to send pills through the mail, but the Supreme Court threw out the case in June over issues of standing. Those plaintiffs say they'll fight on. And a Republican attorney general in Arkansas sent a cease-and-desist letter to a shield law provider.

SHOTS - HEALTH NEWS

Abortion providers back to 'business as usual' after high court's mifepristone ruling

Seago thinks many conservative prosecutors have been hesitant to take legal action, especially in an election year. But he says it's important to act quickly, before abortion by mail becomes pervasive.

The people who are sending these pills know that there's risk in what they're doing. Some providers say they won't travel to or through states with bans so that they can't be subpoenaed, be served legal papers or even be arrested if there's a warrant. That may mean avoiding layovers at Dallas Love Field airport or a detour around those places on a cross-country road trip. For Foster, it means she can't visit her mom and stepdad, who retired to South Carolina.

"The thing about shield laws is that they're new, so we don't have a precedent to go off of," says Lauren Jacobson, a nurse practitioner who prescribes abortion medication through Aid Access, the largest of the four shield law providers. She says she avoids large swaths of the United States. "We don't really know what will or won't happen. But I'm not going to Texas. I've been before though, so that's OK for me."

SHOTS - HEALTH NEWS

Abortion bans still leave a 'gray area' for doctors after Idaho Supreme Court case

Shield laws don't offer blanket protection. The doctors and nurse practitioners who prescribe the pills have malpractice insurance in their states, but it's unclear whether those policies would cover suits from states with abortion restrictions. Patients use third-party payment services like Cash App or PayPal, which are also

untested in how they would work under a shield law. Would they give up information on a provider or patient if requested to do so by law enforcement?

How the experience looks

Lauren, who is 33 and lives in Utah, got pregnant while on birth control and decided that she couldn't afford another child. (NPR is not using her last name because she's worried about professional repercussions.)

Abortion is legal in Utah until 18 weeks, but there are only a handful of clinics in the state. The closest one to Lauren was several hours away by car. Several years prior, she had an abortion at a clinic in Salt Lake City, and it hadn't been a pleasant experience — she had to walk through protesters. The guilt from her conservative Christian upbringing was overwhelming.

Shield law practices account for about 10% of abortions nationwide. There were 9,200 abortions a month provided under shield laws from January to March of this year, according to fresh data from the Society of Family Planning's WeCount project. Some researchers estimate that this number has risen since then and could be as high as 12,000 per month.
Elissa Nadworny/NPR

"I got in my car and I cried," she recalls. "I just never wanted to go through it again."

This time, Lauren got pills from Aid Access, a shield law provider similar to the MAP. "I was a little bit sketched out, I won't lie," she says. "Because like, well, where is this coming from? Who is this under? How are they prescribing this?"

She and her partner did research to try to figure out whether what they were doing was legal. She says ultimately she couldn't find anything that clearly stated that what she wanted to do — have pills sent from an out-of-state doctor — was illegal.

She filled out a form online with questions about how far along she was and her medical history and then connected with a doctor via email and text messages. She googled the doctor, who she found was legit and practicing out of New York.

A few days later, she received abortion medication in the mail and had her abortion at home.

"To do it in the privacy of your own home, where I felt more support as opposed to going through protesters," Lauren says. "Especially with a provider within the state of Utah. I feel like there's always a judgmental indication or undertone."

The online doctor also followed up to make sure everything had gone OK, which Lauren appreciated. "I felt it was a little bit more thorough," she says. "They're checking in on you, like, 'How did you respond? What symptoms? What's going on?'"

A staff member of the MAP brings the boxes containing abortion medication to the local post office.
Elissa Nadworny/NPR

In Massachusetts, the folks who run the MAP hear much the same from their patients. Many emails and messages are logistical, like this email: "I took the first pill on Friday and all the other pills on Saturday. For how long should I be bleeding as I'm still bleeding this morning?"

Many others offer disbelief, relief and gratitude. "I just wanted to say thank you so much," wrote one woman. "I was terrified of this process. It goes against everything I believe in. I'm just not in a place where I can have a child. Thank you for making the pills easily accessible to me."

When Foster, who runs operations for the MAP, does a final tally of the patients who are ready to have their pills sent out, she notices a new note from a woman who just paid, bringing the day's total number of patients from 20 to 21.

"I am a single mother on a fixed income, and I can not afford a kid right now."

It's from a woman in Alabama who is six weeks pregnant and filled out her form around lunchtime. Within an hour, a MAP doctor had reviewed her case and prescribed her the medication. She paid the fee as soon as she was approved. All in all, the whole process took about three hours. Foster is able to pack up those pills and add them to the batch headed to the post office.

By 3 p.m., the Alabama woman's package is scanned by the Postal Service worker.

It's expected to arrive by the week's end.

abortion drugs mifepristone abortion provider misoprostol dobbs v jackson women's health organization roe v. wade

More Stories From NPR

EXHIBIT 65

Abortion providers in Democrat-led states work with Aid Access to funnel pills into antiabortion states

Abortion providers in Democrat-led states work with Aid Access to funnel pills into antiabortion states

washingtonpost.com/politics/2023/07/19/doctors-northeast-launch-abortion-pill-pipeline-into-states-with-bans

July 20, 2023

clockThis article was published more than **1 year ago**

Blue-state doctors launch abortion pill pipeline into states with bans

At least 3,500 doses have been shipped to antiabortion states since mid-June, a process enabled by new shield laws

A doctor reviews mailing labels as she prepares to ship abortion pills from her home in New York's Hudson Valley. (Nadia Sablin for The Washington Post)

11 min

By Caroline Kitchener
July 19, 2023 at 8:19 p.m. EDT

The doctor starts each day with a list of addresses and a label maker.

Sitting in her basement in New York's Hudson Valley, next to her grown children's old bunk beds, she reviews the list of towns and cities she'll be mailing to that day: Baton Rouge, Tucson, Houston.

A month ago, a phone call was the only thing the doctor could offer to women in states with abortion bans who faced unexpected pregnancies. Hamstrung by the laws, she could only coach them through the process of taking abortion pills they received from overseas suppliers.

Then, all of a sudden, the whole system changed. Now she can legally mail them pills herself.

A new procedure adopted in mid-June by one of the largest abortion pill suppliers, Europe-based Aid Access, allows U.S. medical professionals in certain Democratic-led states that have passed abortion "shield" laws to prescribe and mail pills directly to patients in antiabortion states.

Previously, Aid Access allowed only Europe-based doctors to prescribe abortion pills to women in states where abortion is restricted and then shipped those pills internationally, leaving patients to wait weeks. The telemedicine shield laws, enacted over the past year in New York, Massachusetts, Washington, Vermont and Colorado, explicitly protect abortion providers who mail pills to restricted states from inside their borders.

The result is a new pipeline of legally prescribed abortion pills flowing into states with abortion bans. In less than a month, seven U.S.-based providers affiliated with Aid Access — including the Hudson Valley doctor, who spoke on the condition of anonymity because she was concerned for her safety — have mailed 3,500 doses of abortion pills to people in antiabortion states, according to Aid Access, putting just this small group aloneon track to help facilitate at least 42,000 abortions in restricted states over the next year. If more doctors and nurses sign up, as current providers hope they will, the numbers could climb far higher.

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"Everything I'm doing is completely legal," the Hudson Valley doctor said, her family's ping-pong table covered with abortion pills bound for the South and Midwest, where abortion has been largely illegal since the Supreme Court overturned *Roe v. Wade* in June 2022.

"Texas might say I'm breaking their laws, but I don't live in Texas."

The development tees up a complicated interstate battle where doctors on U.S. soil are empowered to legally circumvent abortion laws — allowing blue states to potentially undermine the red state bans that many Republicans hoped would end abortion within their borders. Meanwhile, some conservative groups are angling to outlaw the abortion pill nationwide, attempting to outlaw the medication in the courts as well as calling for a national abortion ban.

The increasing flow of prescribed pills adds to an already expanding underground network for pills being imported from overseas and illegally distributed by abortion rights advocates largely without medical oversight, underscoring the prominent role pills are playing in post-*Roe* America.

The shield laws are “a huge breakthrough for people who need abortions in banned states,” said David Cohen, a Drexel University law professor who focuses on abortion legislation. “Providers are protected in many ways as long as they remain in the state with the shield law.”

Some lawyers say these doctors could face repercussions, even if they steer clear of traveling to states in which abortion bans call for prosecuting abortion providers. At a minimum, some experts said, the question of legal peril could wind up in a gray area ultimately resolved by the courts,such as whether shield law states have the power to block other states from extraditing people charged with crimes.

Major groups that support abortion rights, including Planned Parenthood and the American College of Obstetricians and Gynecologists (ACOG), have been largely silent on the subject of mailing pills from shield law states. Several Aid Access providers say the groups have expressed concern about backing the approach, worried that providers could put themselves at risk.

Molly Meegan, the ACOG’s general counsel and chief legal officer, said the group is “not positioned to provide legal advice to individual members,” adding that “it is wrong for a state to be able to prosecute clinicians and patients in other states where abortion remains legal and unrestricted.” Planned Parenthood issued a statement saying that its advocacy arm was “doing everything possible, and looking into every opportunity, to ensure that patients can access care no matter where they live.”

Jonathan Mitchell, the former solicitor general of Texas and architect of the state’s six-week abortion ban, said it was too early to predict how these shield laws would play out, but said the providers may face consequences.

“There absolutely is a world in which they could get in trouble for it,” he said. “Someone in Texas could do a sting operation and charge them with attempted murder.”

In many states, including Texas, someone found guilty of distributing abortion pills could be sentenced to at least several years in prison. Current abortion bans explicitly exempt those seeking abortions from prosecution, though prosecutors have a history of charging people who have abortions with other crimes.

The Hudson Valley doctor said she’s not worried about her own legal risk. When she arrives at the post office with dozens of new packages every afternoon, she said, no one ever asks any questions.

“Nobody has any idea. I could be doing so many different mailer businesses from home,” she said. “It could be beaded necklaces. It could be soaps. It could be candy.”

Massachusetts passed the first telemedicine abortion shield law of its kind just days after *Roe v. Wade* was overturned. The most recent law passed in New York in mid-June.

The New York law specifies that no state or local government employee “shall cooperate with or provide information to any individual or out-of-state agency or department regarding any legally protected health activity in this state.”

With shield laws, abortion rights advocates have seized an opportunity to "define the landscape," said Julie F. Kay, a human rights lawyer and the legal director of the Abortion Coalition for Telemedicine Access. One key question that could emerge in the coming months is whether prosecutors in any antiabortion states would attempt to extradite medical providers from shield law states, thereby challenging the power of the new laws.

Kay said that traditional extradition laws would be difficult to apply in these circumstances.

"One state can extradite if a person commits the crime in the state, then flees," Kay said. "But no one is fleeing here. You are just sitting in your office in New York."

Aid Access started sending abortion pills to women in the United States long before the June 2022 Supreme Court ruling. The service, which costs $150 or less, is far cheaper than having a surgical abortion or obtaining medication at a clinic — usually between $500 and $800 — making it an appealing option even to people in states where abortion is readily accessible.

Once *Roe* fell, the organization operated in a legal gray area, shipping pills to antiabortion states from India. Aid Access providers mail pills sealed in clearly marked boxes, setting the organization apart from many other overseas pills suppliers, which send pills without a prescription, sometimes unmarked and unsealed.

Demand for pills from Aid Access has soared since the June 2022 Supreme Court ruling, with the organization receiving almost 60 percent more requests for pills this spring than in the months immediately following the decision, according to Abigail Aiken, lead investigator of the Self-managed Abortion Needs Assessment Project at the University of Texas at Austin. People seeking an abortion often find the group online, then make their request through its website. The request gets forwarded to one of the providers.

U.S.-based Aid Access providers were used to the process of receiving and processing requests for abortion pills, accustomed to working with patients in states where abortion is legal — but the process of ordering the medication and mailing it out was far less familiar.

The providers order mifepristone and misoprostol — the pills in a two-step medication abortion regimen — from licensed pill distributors, and ship out the pills to patients fairly quickly along with detailed instructions.

Before the recent change in procedure, the Aid Access providers would send all of their prescriptions to an online pharmacy in California to handle shipping, one of two online pharmacies nationwide that dispenses abortion pills. But neither of those pharmacies is located in a state with a shield law. Until California passes one, a development that is expected this fall, the doctors have to prepare and package the pills bound for restricted states themselves, creating their own labels to stick on the pill boxes they receive, providers said. (Doctors are legally permitted to order and distribute pills on their own, the providers said — it's just not typical.)

"We're medical providers suddenly thrown into this world of shipping," said Lauren Jacobson, a nurse practitioner who operates out of Massachusetts. "Do we write labels by hand? What if we mess up an address? How on earth do we ship 50 packages a day?"

Jacobson concedes that this system is far from perfect. While medication abortion is overwhelmingly safe and effective, she said, on rare occasions her patients in restricted states require in-person care — and they fear the legal risk that could come with a trip to the hospital. In those cases, she said, she will try to help them navigate their state's health-care system safely, searching online for a trustworthy provider and advising them on what to say. Sometimes, she said, she'll go on LinkedIn and scope out the local OB/GYNs, searching for someone who has posted something that supports abortion rights.

"This isn't normal health care," she said. "We don't want to have to do this."

Providers also recognize that many patients prefer or require a surgical procedure to end their pregnancy instead of pills.

One major impetus for Aid Access changing its protocol was the shipping time, said Linda Prine, an Aid Access provider and doctor based in New York. Patients would have to wait weeks for pills shipped from India, she said, often pushing their abortions well into the second trimester — a far more difficult and complicated process. (The U.S. Food and Drug Administration endorses the use of abortion pills up to 10 weeks, though some studies show it's safe and effective to use them significantly later in pregnancy.)

"They were having a really scary miserable experience," Prine said, with some far enough along that they wouldpass a recognizable fetus.

Prine founded the Miscarriage and Abortion Hotline, where people often call with questions about medication abortion. Since Aid Access's protocol change, she said, she has noticed a significant decrease in calls from women who are taking pills in their second trimester.

Eventually, the Aid Access providers fully expect Republicans to take a swing at their efforts.

"We're all like, 'Okay which one of us is going to be the case?'" said the doctor in the Hudson Valley. "It's not if there will be lawsuits, it's when."

Jacobson said she trusts the Massachusetts courts to protect her.

"We have seven American providers who are stepping in and saying, 'You know what, we're not going to be intimidated,'" Jacobson said.

The providers are eagerly waiting for the shield law to pass in California.

Once that passes, the Hudson Valley doctor may no longer have to run a complex shipping operation from her basement. She'll likely be able to send her prescriptions to the pharmacy, just like she used to, she said.

For now, she said, she doesn't mind staying up until 1 a.m. to finish the packing.

"It feels like I'm giving a big middle finger to that part of the country that has done this," she said.

U.S. abortion access, reproductive rights

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